Malaria Rapid Diagnostic Test Performance

Summary results of WHO product testing of malaria RDTs: Round 1-5 (2008-2013)

World Health Organization

FIND
foundation for innovative new diagnostics

CDC

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The WHO Programme of Prequalification of Diagnostics and Medical Devices uses the results of the WHO Malaria RDT Product Testing Programme as the laboratory evaluation component of the prequalification process for malaria RDTs. Although not currently a requirement for WHO procurement, manufacturers are encouraged to apply for WHO prequalification. A regularly updated list of WHO-prequalified diagnostics, including malaria RDTs, is available at *http://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/*.

WHO recommendations for procurement of malaria RDTs are currently based on the attainment of a set of minimum performance criteria in the WHO Malaria RDT Product Testing Programme. These recommendations were established by the WHO Malaria Policy Advisory Committee in 2012 , are outlined in this report and presented in full in a WHO information note (available at *http://www.who.int/malaria/publications/atoz/rdt_selection_criteria_en.pdf?ua=1*).Products that do not meet the full set of minimum performance criteria are not eligible for procurement by WHO.

The lists of RDTs included in this report are not exhaustive lists of malaria RDTs. These lists reflect those products which have been submitted for evaluation in Rounds 2-5 of the WHO Malaria RDT Product Testing Programme, and indicate to what extent these products, as manufactured by the listed companies, were -at the time of their evaluation- found to meet the above mentioned set of minimum performance criteria. The evaluation results indicated in the figures and tables apply only to the specific product as listed with its unique product code / catalogue number and as manufactured by the listed company.

The improper storage, transport and handling of malaria RDTs may affect their level of performance.

The fact that certain products are not included in the lists and figures in this report indicates that they have not or not yet been submitted for evaluation in the WHO Malaria RDT Product Testing Programme, or that their evaluation has not yet been completed and published in [a new edition of this report]. It does not however indicate anything in respect of such products' performance. The lists and figures are updated regularly, and malaria RDTs are added to the lists and figures as and when (following the voluntary participation in the WHO Malaria RDT Product Testing Programme) their evaluation against the above mentioned set of minimum performance criteria has been completed.

Although the malaria RDTs listed in the tables and figures are regularly re-evaluated, and updated evaluation results are published by WHO, WHO cannot represent that products included in the lists and figures will continue to meet the performance criteria in the same manner as indicated. WHO recommends therefore that before procurement of a malaria RDT, each lot of that product undergoes lot testing at one of the two following lot-testing laboratories: Institut Pasteur du Cambodge (IPC), Cambodia or Research Institute for Tropical Medicine (RITM), The Philippines.

WHO disclaims any and all liability and responsibility whatsoever for any injury, death, loss, damage, or other prejudice of any kind that may arise as a result of or in connection with the procurement, distribution and use of any product included in this report and the figures and tables listed on page IV.

This report may not be used by manufacturers and suppliers for commercial or promotional purposes.

Contents

FIGURES

TABLES

1. SUMMARY OF PERFORMANCE OF RAPID DIAGNOSTIC TESTS FOR MALARIA: WHO PRODUCT TESTING ROUNDS 1–5

1.1. Introduction

WHO estimates that half the world's population is at risk of malaria. In 2012, there were an estimated 207 million cases (with an uncertainty range of 135 million to 287 million) and an estimated 627 000 deaths (with an uncertainty range of 473 000 to 789 000). Approximately 90% of all malaria deaths occur in sub-Saharan Africa, and 77% occur in children under 5 years. Malaria remains endemic in 104 countries, and, while parasite-based diagnosis is increasing, most suspected cases of malaria are still not properly confirmed, resulting in over-use of antimalarial drugs and poor disease monitoring (*1*).

WHO recommends that malaria case management be based on parasite diagnosis in all cases (*2*). The use of antigen-detecting rapid diagnostic tests (RDTs) is a vital part of this strategy, forming the basis for extending access to malaria diagnosis by providing parasite-based diagnosis in areas where good-quality microscopy cannot be maintained. The number of RDTs available and the scale of their use have increased rapidly over the past few years; however, limitations of field trials and the heterogeneous nature of malaria transmission have limited the availability of the good-quality data on performance that national malaria programmes require to make informed decisions on procurement and implementation, and it is difficult to extrapolate the results of field trials to different populations and times. Therefore, in 2006, the WHO Special Programme for Research and Training in Tropical Diseases (TDR) and the Foundation for Innovative New Diagnostics (FIND) launched a programme to systematically evaluate and compare the performance of commercially available malaria RDTs. The results of WHO's malaria RDT product testing have been published annually since 2009 and form the basis of the procurement criteria of WHO, other United Nations agencies, the Global Fund to Fight AIDS, Tuberculosis and Malaria, national governments and nongovernmental organizations. The data have guided procurement decisions, which, in turn, have shifted markets towards better-performing tests[1] and are driving overall improvements in the quality of manufacturing.

This summary presents an overview of the results of rounds 1–5 of malaria RDT product testing and key concepts for understanding and using the results. It is published in conjunction with the release of the full report on round 5. The results of all rounds of testing should be considered as a single data set. The separate, full reports of each round (*3–6*) should be consulted for further details of methods, product performance and interpretation of the results.

1.2. The WHO product testing programme

The RDT evaluations summarized here were performed in collaboration by WHO, TDR, FIND, the United States Centers for Disease Control and Prevention (CDC) and other partners.[1] All companies that manufacture according to the ISO 13485:2003 quality system standard were invited to submit one to three products for evaluation in the programme. In each round of testing, products are evaluated against geographically diverse, cryopreserved *Plasmodium falciparum* and *P. vivax* clinical samples diluted to 200 and 2000 parasites/μL and with consistently comparable concentration ranges of histidine-rich protein II (HRP2), *Plasmodium* lactate dehydrogenase (pLDH) and aldolase determined by quantitative enzyme-linked immunosorbent assay (ELISA) (Annex S1). In the first round of testing, 41 products from 21 manufacturers were evaluated against prepared blood panels of cultured *P. falciparum* parasites, while 29, 50, 48 and 42 products from 13, 23, 27 and 34 manufacturers were evaluated in rounds 2, 3, 4 and 5, respectively. Of these 210 products, 206 progressed to testing against panels of patient-derived *P. falciparum* and *P. vivax* parasites and a parasite-negative panel. Thermal stability was assessed after 2 months of storage at elevated temperature and humidity, and a descriptive assessment of ease of use was made. Many manufacturers have decided voluntarily to submit products to one or more rounds of testing, and, in round 5, a requirement was instituted to resubmit products for re-evaluation within 5 years of original testing (Table S1). Of the 206 fully evaluated products, 32 have been evaluated twice, 11 have been evaluated three times and two evaluated four times in rounds 1–5. Of the 147 unique products tested in the programme, 36 detect *P. falciparum* alone, 101 detect and differentiate *P. falciparum* from non-*P. falciparum* malaria (either pan-specific or species-specific for *P. vivax* or *P. vivax*, *ovale* and *malariae*), 9 detect *P. falciparum* and non-*P. falciparum* malaria without distinguishing between them, and one product was designed to detect *P. vivax* only. Manufacturers submitted two lots of each product for evaluation. When the same products (*7*) were resubmitted in subsequent rounds of testing, the second set of results replaced those from the earlier round. Thus, the performance of some tests in the results below differs from that reported in rounds 1–4.

Of the 22 products due for compulsory retesting in round 5, 10 were submitted (Table S1). Round 1 products that were not

[1] See full reports of rounds 1–5 (3–6) for lists of collaborating partners.

resubmitted have been removed from the figures and tables in this summary performance document.

The aim of the evaluation is to provide comparative data on the performance of the submitted production lots of each product. These data will be used to guide procurement decisions by WHO, other United Nations agencies and national governments and constitute the laboratory evaluation component of the WHO prequalification process for malaria RDTs (*8*). Product testing is part of a continuing programme of work to improve the quality of RDTs in use and to ensure reliable malaria diagnosis in areas where malaria is prevalent. A sixth round of product testing will begin in June 2014.

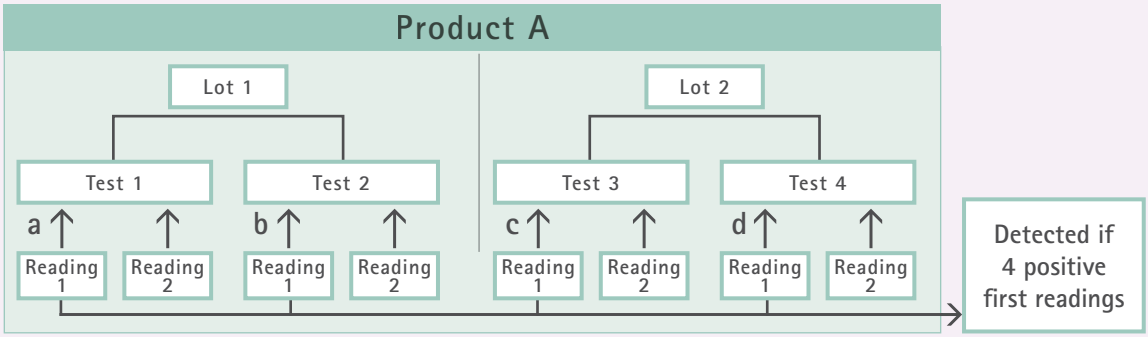
1.3. Panel detection score and other results of the evaluation

The results (summarized in Figs S1–S3 and Tables S2 and S3) provide comparative data on two lots of products against a panel of parasite samples diluted to a low parasite density (200 parasites/µL) and a higher parasite density (2000 or 5000 parasites/µL). The former is well below the mean parasite density found in many populations with endemic malaria and is considered close to the threshold that must be detected in order reliably to identify clinical malaria in many settings (*9*). For the purposes of this report, the main measure of performance is the panel detection score (PDS);[1] for each RDT evaluated, the PDS is measured separately at the

[1] Termed "detection rate" in the full report of round 1, published in 2009.

Box 1: Example calculation of panel detection score and positivity rate for product A against a sample density of 200 parasites/µL

The first reading was at the minimum time specified by the manufacturer; the second reading was up to 30 min later[a]. A sample is considered detected only if all first test readings, from both lots, are positive, i.e. readings a, b, c and d must be positive.



[a] second reading results are for internal use only

P. falciparum sample	a	b	c	d	
1	+	–	+	+	Sample NOT detected
2	+	–	–	+	Sample NOT detected
3	+	+	+	+	Sample detected

In this example, only one of three samples was positive all four times it was tested; the PDS is therefore 1/3 = 33%.

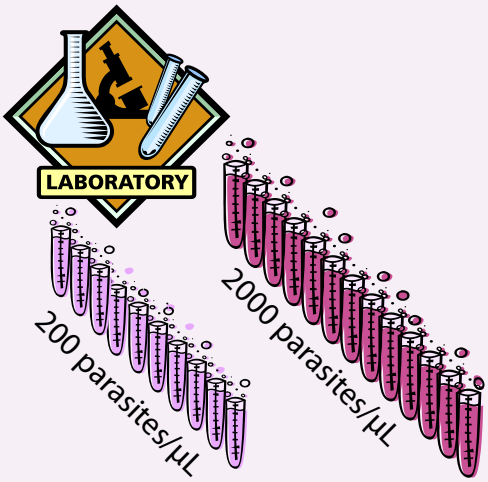
The positivity rate is calculated as the percentage of all tests of a particular product that returned a positive test result at the manufacturers' recommended minimum reading time when tested against a *P. falciparum* or *P. vivax* sample.

In the above example, the positivity rate is: 9/12 = 75%.

The positivity rate is always greater than the PDS, except when the PDS and the positivity rate are both 100%.

Box 2: Performance measures in WHO product testing and in field settings: PDS versus clinical sensitivity

WHO Malaria RDT Product Testing
Primary performance measure: PDS indicates which products are likely to be more sensitive in the field, particularly in populations with low-density infections.



Reference panels: two fixed parasite densities allows discrimination in RDT performance.

Malaria endemic setting
Performance measure: sensitivity is the proportion of the population studied who have malaria for whom the test is positive.

- high, moderate, low transmission
- immune, non-immune
- vulnerable groups

Patients have varying parasite density. Most RDTs for *P. falciparum* and *P. vivax* perform well for a parasite density > 2000 parasites/µL, but clinically significant densities < 200 parasites/µL may be missed. The "overall" test performance will nevertheless be classified as very good in a field evaluation.

lower and the higher parasite density. The summary figures also show the false-positive rates against blood samples containing no malaria parasites or known markers of other diseases and the rate of invalid results.

The PDS is the percentage of malaria samples in the panel that give a positive result in two RDTs per lot at the lower parasite density or by a single RDT per lot at the higher parasite density. As each sample is tested with RDTs from two lots, for a sample to be positive at the lower parasite density, it must show a positive result in four tests (two RDTs per lot for two lots); at the higher parasite density, it must show a positive result in two tests (one RDT per lot for two lots). Thus, the PDS is a combined measure of positivity rate, incorporating inter-test and inter-lot consistency. As all tests performed on each sample must show a positive result for the sample to be considered positive, the PDS for a given RDT will usually be lower than a simple positivity rate per panel, measured by comparing the number of positive tests among all tests performed per panel. The PDS is also different from clinical sensitivity: the ability of the test to detect malaria infection in a given population of infected patients. Boxes 1 and 2 illustrate how the PDS is calculated and how it differs from a simple positivity rate for all samples tested and from clinical sensitivity in a population.

The PDS for a given RDT is different from the clinical sensitivity of that RDT (also called the true positive rate), which is a measure of the proportion of people known to have the disease who test positive for it. The sensitivity of malaria RDTs is highly dependent on local conditions, including the parasite density in the population; it therefore varies among populations with different levels of transmission, as their level of immunity affects the parasite density at which they exhibit symptoms that warrant a diagnostic test. Where transmission rates are low, the parasite densities in people with symptoms of malaria are likely to be low, and tests will be less sensitive. Test performance at 200 parasites/µL is therefore particularly important. The results in this report show the comparative performance of RDTs and indicate which products are likely to be more sensitive in the field, particularly in populations with low-density infections.

In general, as countries reduce the prevalence of malaria and even move towards malaria elimination, detection of low parasite densities becomes increasingly important in case management. As the high PDS at 2000 parasites/µL indicates, the sensitivity of many of these products is similar in populations with higher parasite densities and therefore it is not possible to discriminate RDTs with superior performance.

An important caveat to estimating field sensitivity from the PDS provided in this report is that the panels used include only parasites known to express the target antigens. While non-expression of the target antigens has not been recorded for aldolase or pLDH, it is known that parasites that infect people in some areas of South America and India do not express HRP2 (*10*, *11*). In areas where HRP2-deleted parasites exist, tests for HRP2 will have greatly reduced sensitivity or be incapable of detecting *P. falciparum*. In such populations, only tests for pLDH or aldolase in *P. falciparum* parasites will be effective for diagnosing falciparum malaria.

Heat stability (summarized in Table S3) is vital to maintaining the sensitivity of tests in the field. As a result, for procurement, careful consideration must be given to ensure that the products to be used in areas with high temperatures of transport and storage have demonstrated stability in the product testing programme. Requirements vary among countries; for example, if tests are to be deployed in areas where temperatures rarely rise above 30 °C, less emphasis is needed on stability at high temperatures than on other aspects of quality.

Ease-of-use requirements depend on the extent of training and the work environment of the users. Particularly in primary health care settings, the simpler the test, the easier it will be to avoid errors in preparation and interpretation.

Detailed results can be found in the report of each evaluation (*3*–*6*) and at http://www.who.int/malaria/publications/diagnostic_testing/en/.

1.4. Summary of outcomes

This laboratory-based evaluation provides a comparative, standardized measure of RDT performance for distinguishing between well and poorly performing tests to serve as a basis for procurement decisions by malaria control programmes and to guide United Nations procurement policy.

In round 5, the proportion of tests that achieved a PDS ≥ 75% at 200 parasites/µL is comparable to those in rounds 3 and 4 for *P. falciparum* (78.6%); that for *P. vivax*, 42.4%, is similar to that in round 4.

Several RDTs in the five rounds of testing consistently detected malaria at a low parasite density (200 parasites/µL), had low false-positive rates, are stable at tropical temperatures, are relatively easy to use and can detect *P. falciparum* or *P. vivax* infections or both.

Although the performance of the products varied widely at low parasite density (200 parasites/µL), all products had a high rate of detection of *P. falciparum* at 2000 or 5000 parasites/µL, as did the majority of products for *P. vivax* at 2000 parasites/µL.

P. falciparum tests that target the HRP2 antigen had the highest detection rates, and two previously evaluated tests that target pan-pLDH for detection of *Plasmodium spp.* infection also achieved a good PDS. In round 5, the two poorest performing tests for detection of *P. falciparum* were based on *P. falciparum*-specific pLDH detection. Thus, the choice of well-performing pLDH-based *P. falciparum* tests remains limited, as it does for pan-only-specific tests.

Test performance sometimes varied between lots and widely between similar products, confirming the advisability of testing lots after purchase and before use in the field. Furthermore, anomalies that interfered with test interpretation were regularly recorded during round 5 (Annex S2). All products had issues with red background and with incomplete clearing, and cases of samples failing to flow or migrate on the RDT were reported for 62% of products.

Ninety-eight percent of the RDTs evaluated in round 5 were in cassette format.

With regard to products retested under the compulsory resubmission requirement, one showed improved (4.8%) detection of *P. falciparum* and one improved (4.3%) detection of *P. vivax*, while six and two had diminished performance (> 5% decrease) for detection of *P. falciparum* (mean, 13.9%; median, 8.4%) and *P. vivax* (mean, 8.5%), respectively. All products except one had the same or lower false-positive rates (mean improvement, 3.7%).

1.5. How can product testing results inform RDT procurement and use?

Accurate diagnosis is vital to good malaria case management, whether based on microscopy or RDTs. The results of this report should be used to identify a short list of RDTs for procurement for use in settings where good microscopy is not available or appropriate. Box 3 lists WHO's minimum criteria for RDT selection, and Annex S3 provides a step-by-step approach to selecting an RDT, taking into consideration local malaria transmission and illness where the tests will be used (e.g. *Plasmodium* species, target antigen, parasite densities, climate) and other important considerations, including ease of use in the field (Annex S2), training or retraining requirements and lot testing.[1]

The tabular results in TableS2 are colour-coded to reflect achievement of WHO performance requirements for RDT procurement, and a web-based tool that allows filtering of product testing results by various parameters to assist in selecting products with the performance characteristics most suitable for a country's health programme is available and maintained by FIND (*12*). Comprehensive guidance on several aspects of procurement can be found in *Good practices for selecting and procuring rapid diagnostic tests for malaria* and guidance on implementation in *Universal access to malaria diagnosis* (*13*, *14*).

[1] The WHO-FIND malaria RDT evaluation programme provides lot-testing capacity in two regional laboratories free of charge; it can be accessed at *malaria_rdt@who.int* and *info@finddiagnostics.org.*

1.6. Product testing and WHO programme for prequalification of diagnostics and medical devices

The WHO prequalification of diagnostics and medical devices programme uses the results of product testing as the laboratory evaluation component of the prequalification process for malaria RDTs. These data are used to set priorities for dossier review and inspection. Although prequalification is not currently a requirement for WHO procurement, manufacturers are encouraged to apply for it. A list of prequalified diagnostics, including malaria RDTs, is available at *http://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/*.

Box 3: WHO selection criteria for the procurement of RDTs

Products should be selected in line with the following set of criteria, based on the results of the assessment of the WHO Malaria RDT Product Testing Programme:

(A) For the detection of *Plasmodium falciparum* (Pf) in all transmission settings the panel detection score (PDS) against Pf samples should be at least 75% at 200 parasites/µL.

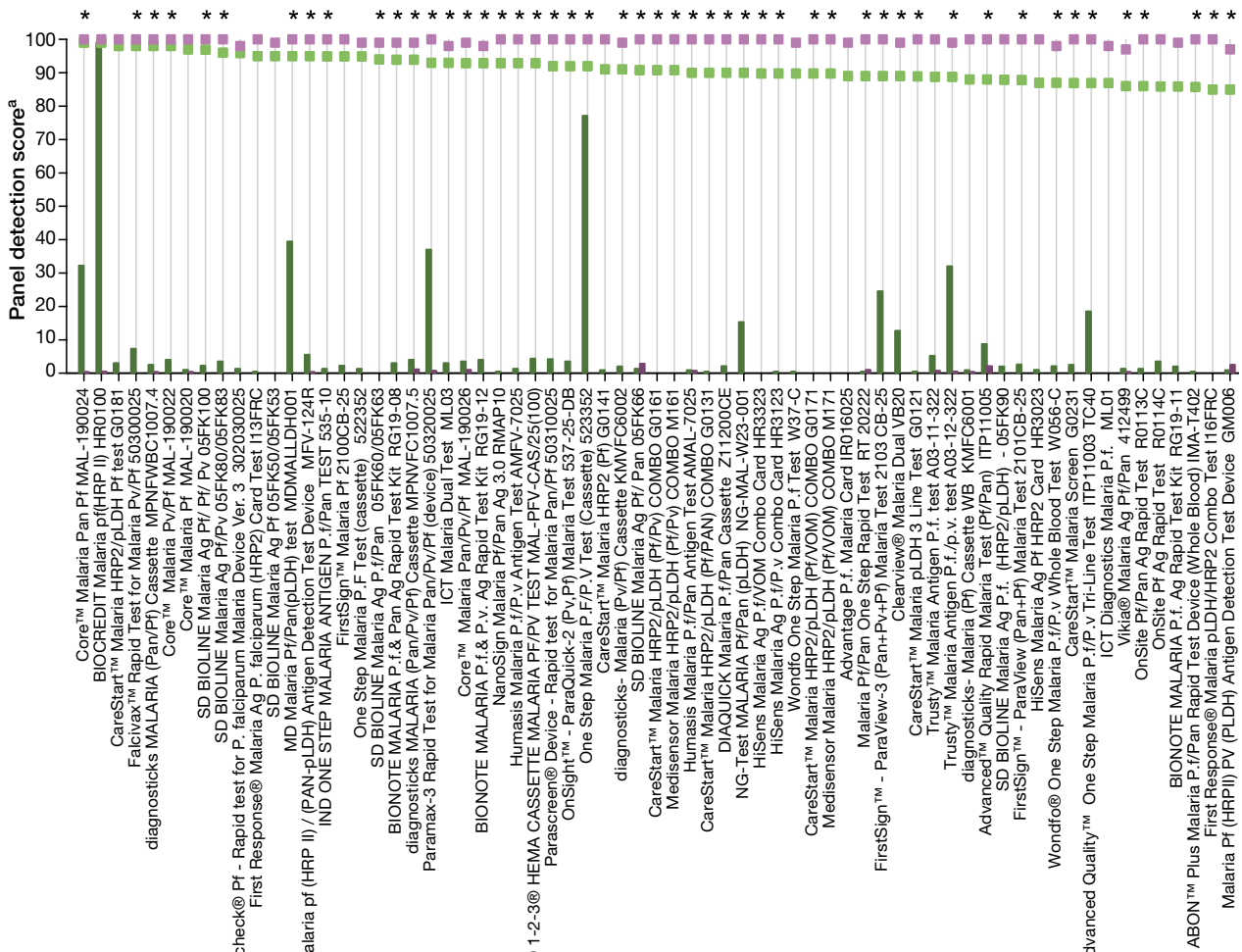
(B) For the detection of *Plasmodium vivax* (Pv) in all transmission settings the panel detection score (PDS) against Pv samples should be at least 75% at 200 parasites/µL.

(C) The false positive rate should be less than 10%.

(D) The invalid rate should be less than 5%.

Only products meeting performance criteria outlined in A,B,C and D are recommended for procurement

Figure S1: Malaria RDT performance in phase 2 of rounds 2–5 against wild-type (clinical) samples containing *P. falciparum* at low (200) and high (2000–5000) parasite density (parasites/µL) and clean-negative samples



[a] Panel detection score: A sample is considered detected only if all RDTs from both lots read by the first technician, at the minimum specified reading time, are positive.

[b] Clean-negative, blood samples from healthy volunteers with no known current illness or blood abnormality.

* Indicates tests that also detect other non-*P. falciparum* parasites

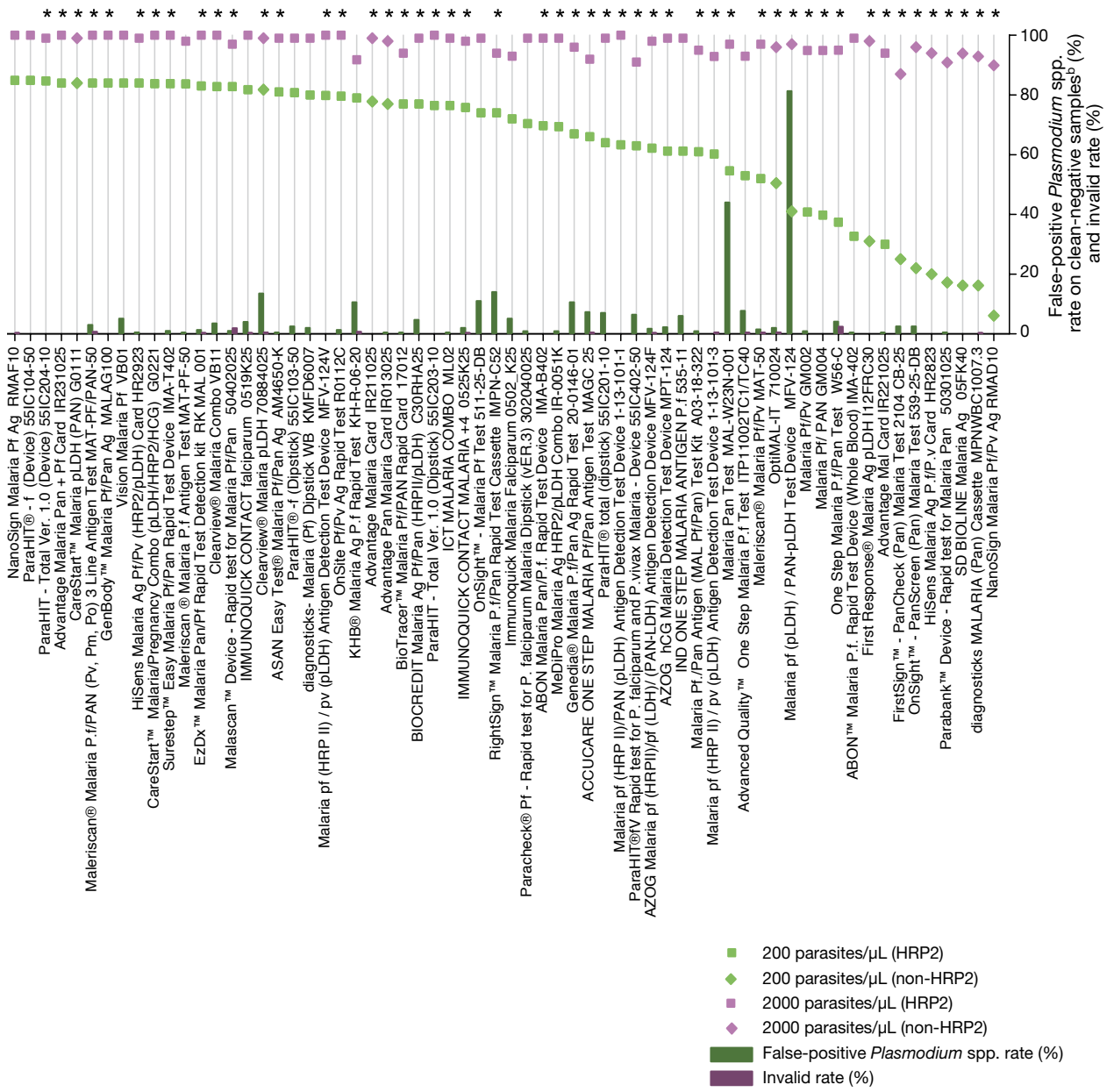
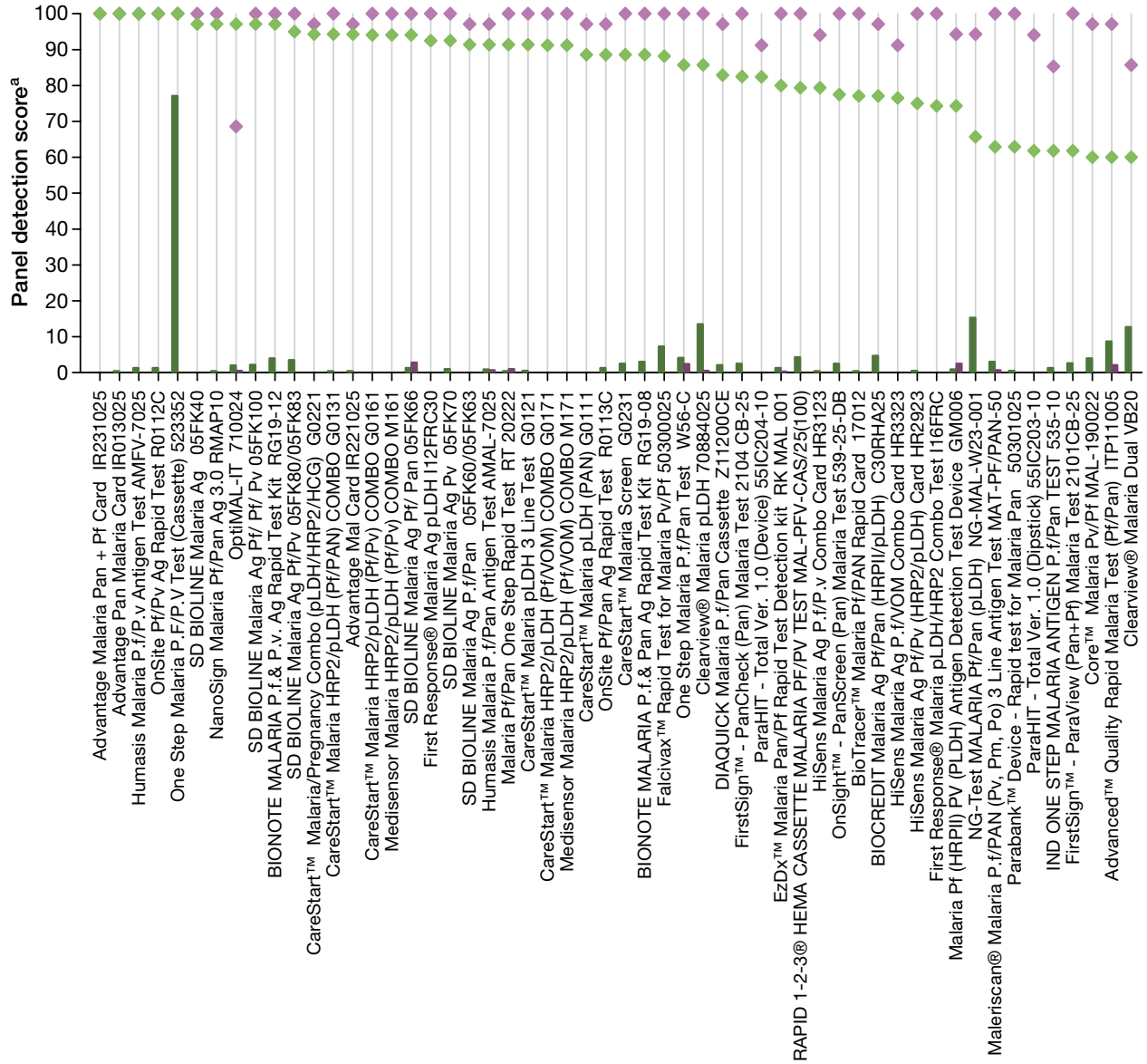

False-positive Plasmodium spp. rate on clean-negative samples[b] (%) and invalid rate (%)
0
20
40
60
80
100
NanoSign Malaria Pf Ag RMAF10
ParaHIT® -f (Device) 55IC104-50
ParaHIT - Total Ver. 1.0 (Device) 55IC204-10
Advantage Malaria Pan + Pf Card IR231025
CareStart™ Malaria pLDH (PAN) G0111
Maleriscan® Malaria P.f/PAN (Pv, Pm, Po) 3 Line Antigen Test MAT-PF/PAN-50
GenBody™ Malaria Pf/Pan Ag MALAG100
Vision Malaria Pf VB01
HiSens Malaria Ag Pf/Pv (HRP2/pLDH) Card HR2923
CareStart™ Malaria/Pregnancy Combo (pLDH/HRP2/HCG) G0221
Surestep™ Easy Malaria Pf/Pan Rapid Test Device IMA-T402
Maleriscan ® Malaria P.f Antigen Test MAT-PF-50
EzDx™ Malaria Pan/Pf Rapid Test Detection kit RK MAL 001
Clearview® Malaria Combo VB11
Malascan™ Device - Rapid test for Malaria Pf/Pan 50402025
IMMUNOQUICK CONTACT falciparum 0519K25
Clearview® Malaria pLDH 70884025
ASAN Easy Test® Malaria Pf/Pan Ag AM4650-K
ParaHIT®-f (Dipstick) 55IC103-50
diagnosticks- Malaria (Pf) Dipstick WB KMFD6007
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device MFV-124V
OnSite Pf/Pv Ag Rapid Test R0112C
KHB® Malaria Ag P.f Rapid Test KH-R-06-20
Advantage Malaria Card IR211025
Advantage Pan Malaria Card IR013025
BioTracer™ Malaria Pf/PAN Rapid Card 17012
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH) C30RHA25
ParaHIT - Total Ver. 1.0 (Dipstick) 55IC203-10
ICT MALARIA COMBO ML02
IMMUNOQUICK CONTACT MALARIA +4 0525K25
OnSight™ - Malaria Pf Test 511-25-DB
RightSign™ Malaria P.f/Pan Rapid Test Cassette IMPN-C52
Immunoquick Malaria Falciparum 0502_K25
Paracheck® Pf - Rapid test for P. falciparum Malaria Dipstick (vER.3) 302040025
ABON Malaria Pan/P.f. Rapid Test Device IMA-B402
MeDiPro Malaria Ag HRP2/pLDH Combo IR-0051K
Genedia® Malaria P.f/Pan Ag Rapid Test 20-0146-01
ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test MAGC 25
ParaHIT® total (dipstick) 55IC201-10
Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device 1-13-101-1
ParaHIT®fV Rapid test for P. falciparum and P.vivax Malaria - Device 55IC402-50
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device MFV-124F
AZOG hCG Malaria Detection Test Device MPT-124
IND ONE STEP MALARIA ANTIGEN P.f 535-11
Malaria Pf./Pan Antigen (MAL Pf/Pan) Test Kit A03-18-322
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device 1-13-101-3
Malaria Pan Test MAL-W23N-001
Advanced Quality™ One Step Malaria P.f Test ITP11002TC1/TC40
Maleriscan® Malaria Pf/Pv MAT-50
OptiMAL-IT 710024
Malaria pf (pLDH) / PAN-pLDH Test Device MFV-124
Malaria Pf/Pv GM002
Malaria Pf/ PAN GM004
One Step Malaria P.f/Pan Test W56-C
ABON™ Malaria P.f. Rapid Test Device (Whole Blood) IMA-402
First Response® Malaria Ag pLDH I12FRC30
Advantage Mal Card IR221025
FirstSign™ - PanCheck (Pan) Malaria Test 2104 CB-25
OnSight™ - PanScreen (Pan) Malaria Test 539-25-DB
HiSens Malaria Ag P.f/P.v Card HR2823
Parabank™ Device - Rapid test for Malaria Pan 50301025
SD BIOLINE Malaria Ag 05FK40
diagnosticks MALARIA (Pan) Cassette MPNWBC1007.3
NanoSign Malaria Pf/Pv Ag RMAD10
200 parasites/µL (HRP2)
200 parasites/µL (non-HRP2)
2000 parasites/µL (HRP2)
2000 parasites/µL (non-HRP2)
False-positive Plasmodium spp. rate (%)
Invalid rate (%)

Figure S2: Malaria RDT performance in phase 2 of rounds 2–5 against wild-type (clinical) samples containing *P. vivax* at low (200) and high (2000 or 5000) parasite density (parasites/µL) and clean-negative samples



[a] Panel detection score - A sample is considered detected only if all RDTs from both lots read by the first technician, at the minimum specified reading time, are positive.

[b] Clean-negative - blood samples from healthy volunteers with no known current illness or blood abnormality.

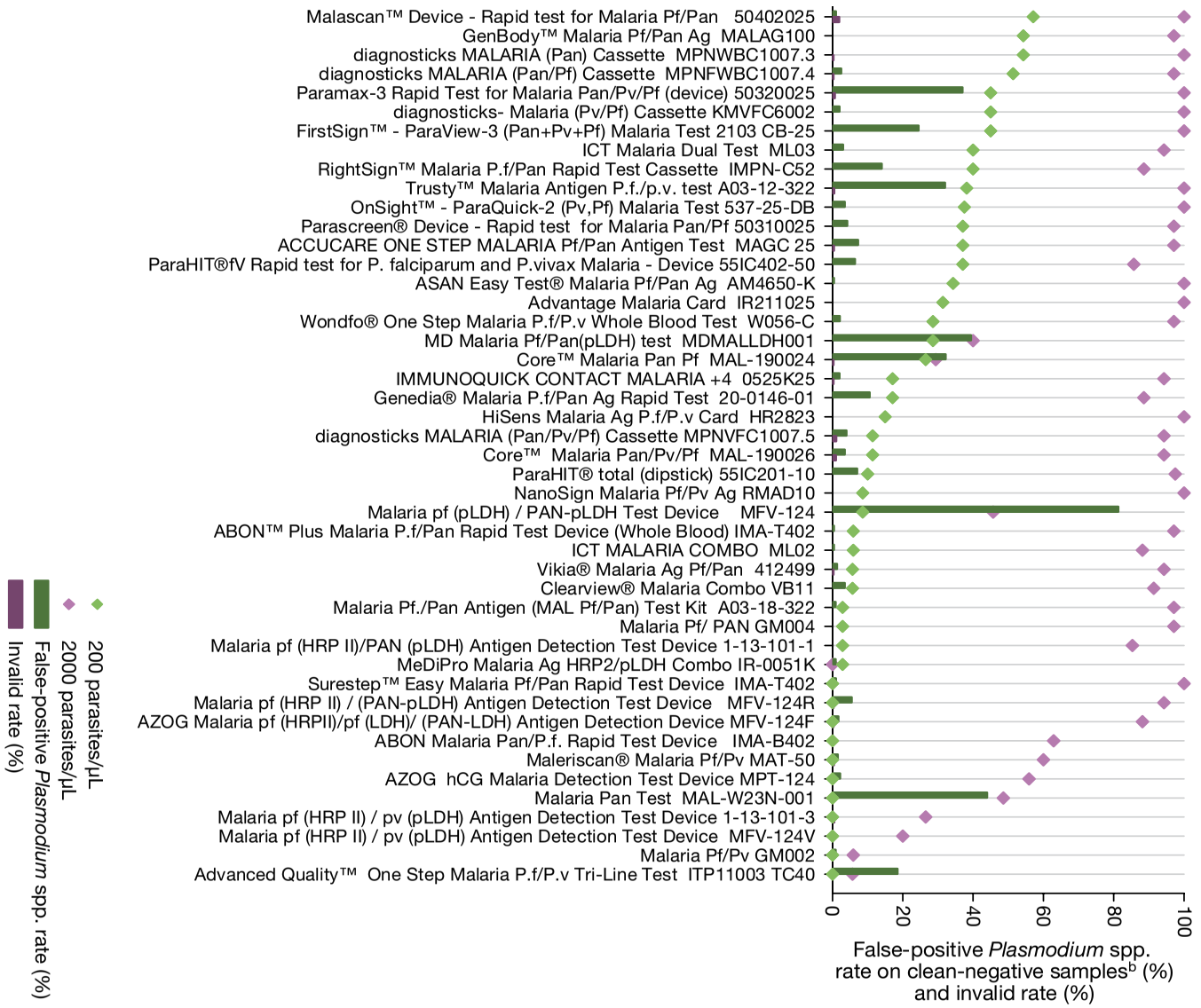
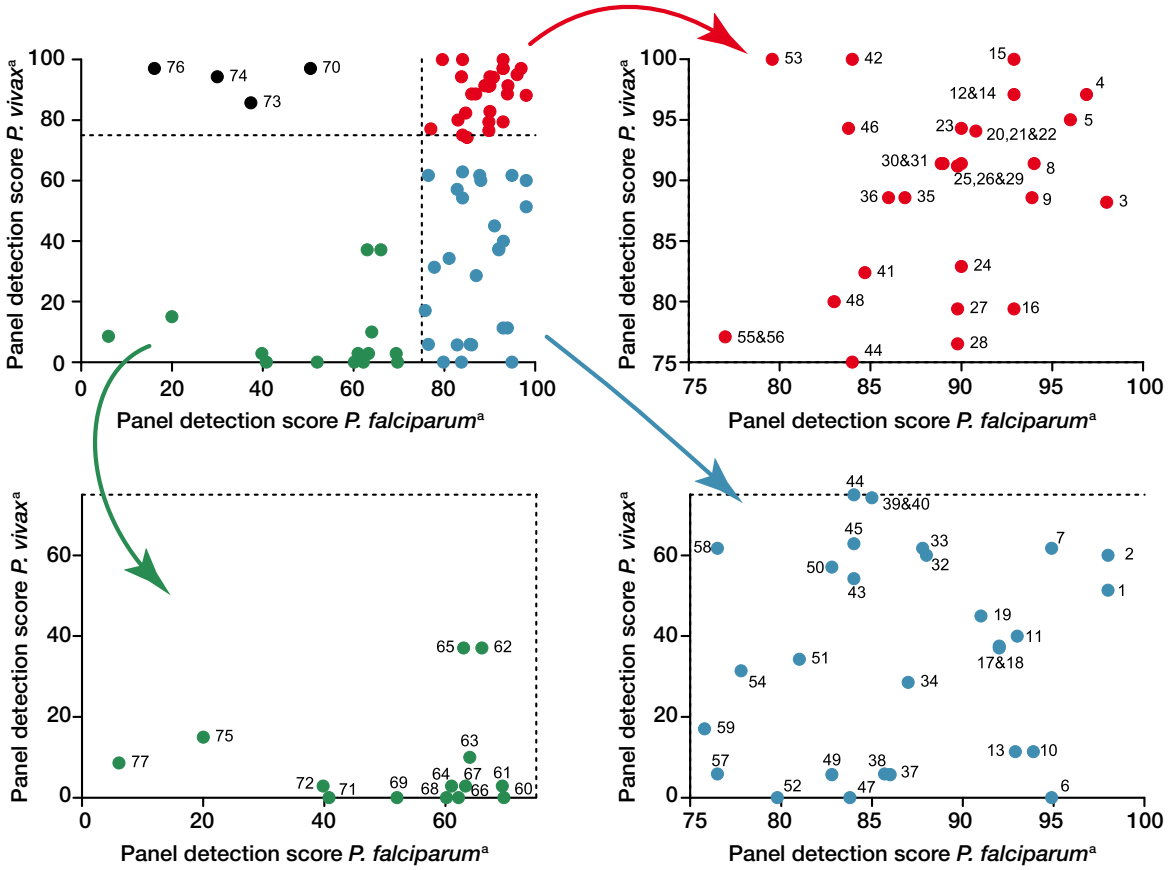

Malascan™ Device - Rapid test for Malaria Pf/Pan 50402025
GenBody™ Malaria Pf/Pan Ag MALAG100
diagnosticks MALARIA (Pan) Cassette MPNWBC1007.3
diagnosticks MALARIA (Pan/Pf) Cassette MPNFWBC1007.4
Paramax-3 Rapid Test for Malaria Pan/Pv/Pf (device) 50320025
diagnosticks- Malaria (Pv/Pf) Cassette KMVFC6002
FirstSign™ - ParaView-3 (Pan+Pv+Pf) Malaria Test 2103 CB-25
ICT Malaria Dual Test ML03
RightSign™ Malaria P.f/Pan Rapid Test Cassette IMPN-C52
Trusty™ Malaria Antigen P.f./p.v. test A03-12-322
OnSight™ - ParaQuick-2 (Pv,Pf) Malaria Test 537-25-DB
Parascreen® Device - Rapid test for Malaria Pan/Pf 50310025
ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test MAGC 25
ParaHIT®fV Rapid test for P. falciparum and P.vivax Malaria - Device 55IC402-50
ASAN Easy Test® Malaria Pf/Pan Ag AM4650-K
Advantage Malaria Card IR211025
Wondfo® One Step Malaria P.f/P.v Whole Blood Test W056-C
MD Malaria Pf/Pan(pLDH) test MDMALLDH001
Core™ Malaria Pan Pf MAL-190024
IMMUNOQUICK CONTACT MALARIA +4 0525K25
Genedia® Malaria P.f/Pan Ag Rapid Test 20-0146-01
HiSens Malaria Ag P.f/P.v Card HR2823
diagnosticks MALARIA (Pan/Pv/Pf) Cassette MPNVFC1007.5
Core™ Malaria Pan/Pv/Pf MAL-190026
ParaHIT® total (dipstick) 55IC201-10
NanoSign Malaria Pf/Pv Ag RMAD10
Malaria pf (pLDH) / PAN-pLDH Test Device MFV-124
ABON™ Plus Malaria P.f/Pan Rapid Test Device (Whole Blood) IMA-T402
ICT MALARIA COMBO ML02
Vikia® Malaria Ag Pf/Pan 412499
Clearview® Malaria Combo VB11
Malaria Pf./Pan Antigen (MAL Pf/Pan) Test Kit A03-18-322
Malaria Pf/ PAN GM004
Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device 1-13-101-1
MeDiPro Malaria Ag HRP2/pLDH Combo IR-0051K
Surestep™ Easy Malaria Pf/Pan Rapid Test Device IMA-T402
Malaria pf (HRP II) / (PAN-pLDH) Antigen Detection Test Device MFV-124R
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device MFV-124F
ABON Malaria Pan/P.f. Rapid Test Device IMA-B402
Maleriscan® Malaria Pf/Pv MAT-50
AZOG hCG Malaria Detection Test Device MPT-124
Malaria Pan Test MAL-W23N-001
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device 1-13-101-3
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device MFV-124V
Malaria Pf/Pv GM002
Advanced Quality™ One Step Malaria P.f/P.v Tri-Line Test ITP11003 TC40
0
20
40
60
80
100
False-positive Plasmodium spp. rate on clean-negative samples[b] (%) and invalid rate (%)
200 parasites/µL
2000 parasites/µL
False-positive Plasmodium spp. rate (%)
Invalid rate (%)

Figure S3: Panel detection score of malaria combination and pan-only RDTs, meeting WHO procurement criteria for false-positive and invalid rates, in phase 2 of rounds 2-5 against wild-type (clinical) samples containing *P. falciparum* and *P. vivax* at low (200) parasite density (parasites/µL)



1 diagnosticks MALARIA (Pan/Pf) Cassette- MPNFWBC1007.4
2 Core™ Malaria Pv/Pf - MAL-190022
3 FalciVax™ - Rapid test for Malaria Pv/Pf - 50300025
4 SD BIOLINE Malaria Ag Pf/ Pf/ Pv - 05FK100
5 SD BIOLINE Malaria Ag Pf/Pv - 05FK80/05FK83
6 Malaria pf (HRP II) / (PAN-pLDH) Antigen Detection Test Device - MFV-124R
7 IND ONE STEP MALARIA ANTIGEN P.f/Pan TEST - 535-10
8 SD BIOLINE Malaria Ag P.f/Pan - 05FK60/05FK63
9 BIONOTE MALARIA P.f.& Pan Ag Rapid Test Kit - RG19-08
10 diagnosticks MALARIA (Pan/Pv/Pf) Cassette - MPNVFC1007.5
11 ICT Malaria Dual Test - ML03
12 BIONOTE MALARIA P.f.& P.v. Ag Rapid Test Kit - RG19-12
13 Core™ Malaria Pan/Pv/Pf - MAL-190026
14 NanoSign Malaria pf/pan Ag 3.0 - RMAP10
15 Humasis Malaria P.f/P.v Antigen Test - AMFV-7025
16 RAPID 1-2-3® HEMA CASSETTE MALARIA PF/PV TEST - MAL-PFV-CAS/25(100)
17 Parascreen® - Rapid test for Malaria Pan/Pf - 50310025
18 OnSight™ - ParaQuick-2 (Pv,Pf) Malaria Test - 537-25-DB
19 diagnosticks- Malaria (Pv/Pf) Cassette - KMVFC6002
20 CareStart™ Malaria HRP2/pLDH (Pf/Pv) COMBO - G0161
21 Medisensor Malaria HRP2/pLDH (Pf/Pv) COMBO - M161
22 SD BIOLINE Malaria Ag Pf/ Pan - 05FK66
23 CareStart™ Malaria HRP2/pLDH (Pf/PAN) COMBO - G0131
24 DIAQUICK Malaria P.f/Pan Cassette - Z11200CE
25 Humasis Malaria P.f/Pan Antigen Test - AMAL-7025
26 CareStart™ Malaria HRP2/pLDH (Pf/VOM) COMBO - G0171
27 HiSens Malaria Ag P.f/P.v Combo Card - HR3123
28 HiSens Malaria Ag P.f/VOM Combo Card - HR3323
29 Medisensor Malaria HRP2/pLDH (Pf/VOM) COMBO - M171
30 Malaria Pf/Pan One Step Rapid Test - RT 20222
31 CareStart™ Malaria pLDH 3 Line Test - G0121
32 Advanced Quality™ Rapid Malaria Test (Pf/Pan) - ITP11005
33 FirstSign™ ParaView (Pan+Pf) - 2101CB-25
34 Wondfo® One Step Malaria P.f/P.v Whole Blood Test - W056-C
35 CareStart™ Malaria Screen - G0231
36 OnSite Pf/Pan Ag Rapid Test - R0113C
37 Vikia® Malaria Ag Pf/Pan - 412499
38 ABON™ Plus Malaria P.f/Pan Rapid Test Device (Whole Blood) - IMA-T402
39 First Response® Malaria Ag. pLDH/HRP2 Combo Card Test - I16FRC
40 Malaria Pf (HRPII)/ PV (PLDH) Antigen Detection Test Device - GM006
41 ParaHIT - Total Ver. 1.0 (Device) - 55IC204-10
42 Advantage Malaria Pan + Pf Card - IR231025
43 GenBody™Malaria Pf/Pan Ag - MALAG100
44 HiSens Malaria Ag Pf/Pv (HRP2/pLDH) Card - HR2923
45 Maleriscan® Malaria Pf/PAN (Pv, Pm, Po) 3 Line Antigen Test - MAT-PF/PAN-50
46 CareStart™ Malaria/Pregnancy Combo (pLDH/HRP2/HCG) - G0221
47 Surestep™ Easy Malaria Pf/Pan Rapid Test Device - IMA-T402
48 EzDx™ Malaria Pan/Pf Rapid Test Detection kit - RK MAL 001
49 Clearview® Malaria Combo - VB11
50 Malascan™ Device - Rapid test for Malaria Pf/Pan - 50402025
51 ASAN Easy Test® Malaria Pf/Pan Ag - AM4650-K
52 Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device - MFV-124V
53 OnSite Pf/Pv Ag Rapid Test - R0112C
54 Advantage Malaria Card - IR211025
55 BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH) - C30RHA25
56 BioTracer™ Malaria Pf/PAN Rapid Card - 17012
57 ICT MALARIA COMBO - ML02
58 ParaHIT - Total Ver. 1.0 (Dipstick) - 55IC203-10
59 IMMUNOQUICK CONTACT MALARIA +4 - 0525K25
60 ABON Malaria Pan/P.f. Rapid Test Device - IMA-B402
61 MeDiPro Malaria Ag HRP2/pLDH Combo - IR-0051K
62 ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test - MAGC 25
63 ParaHIT® total (dipstick) - 55IC201-10
64 Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device - 1-13-101-1
65 ParaHIT®fV Rapid test for P. falciparum and P.vivax Malaria - Device - 55IC402-5
66 AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device - MFV-124F
67 Malaria Pf./Pan Antigen (MAL Pf/Pan) Test Kit - A03-18-322
68 Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device - MFV-124V
69 Maleriscan® Malaria Pf/Pv - MAT-50
70 OptiMAL-IT - 710024
71 Malaria Pf/Pv - GM002
72 Malaria Pf/ PAN - GM004
73 One Step Malaria P.f/Pan Test - W56-C
74 Advantage Mal Card - IR221025
75 HiSens Malaria Ag P.f/P.v Card - HR2823
76 SD BIOLINE Malaria Ag - 05FK40
77 NanoSign Malaria Pf/Pv Ag - RMAD10

[a] Panel detection score - A sample is considered detected only if all RDTs from both lots read by the first technician, at the minimum specified reading time, are positive.

Table S1: Product resubmissions: WHO malaria RDT product testing rounds 1–5

Manufacturer	Product name	Catalogue No.	Product re-submission Round	
			Voluntary	Compulsory
Access Bio, Inc.	CareStart™ Malaria HRP2/PLDH (Pf/Pv) COMBO	G0161	2, 4	
	CareStart™ Malaria HRP2/PLDH (Pf/VOM) COMBO	G0171	2, 4	
	CareStart™Malaria HRP2 (Pf)	G0141	1	5
	CareStart™ Malaria HRP2/pLDH (Pf/PAN) Combo	G0131	1	5
	CareStart™Malaria pLDH (PAN)	G0111	1	5
Advy Chemical Pvt. Ltd. (Affiliate of Bharat Serums & Vaccines Ltd.)	EzDx™ Malaria Pan/Pf Rapid Test Detection Kit	RK MAL 001	4, 5	
Biosynex	IMMUNOQUICK® MALARIA *falciparum*	0502_K25	1	5
AZOG	Malaria pf (HRP II) / (PAN-LDH) Antigen Detection Test Device[a]	MFV-124R	1, 3	
	Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	3, 5	
Bhat Bio-Tech India (P) Ltd.	Maleriscan® Malaria Pf/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	4, 5	
Bioland	NanoSign Malaria Pf/Pan Ag	RMAP10	3, 4	
Blue Cross Bio-Medical (Beijing) Co., Ltd.	One Step Malaria Pf Test (cassette)	522352	2, 3, 4	
	One Step Malaria P.F/P.V Test (Cassette)	523352	4, 5	
CTK Biotech, Inc.	Onsite Pf Ag Rapid Test	R0114C	2, 3	
	Onsite Malaria Pf/Pan Malaria Ag Rapid Test	R0113C	2, 3, 4, 5	
	Onsite Malaria Pf/Pv Ag Rapid Test	R0112C	2, 3, 4	
DiaMed - A Division of Bio-Rad	OptiMAL-IT	710024	1, 3	
Guangzhou Wondfo Biotech Co. Ltd.	Wondfo One Step Malaria Pf/Pan Whole Blood Test	W56-C	1, 3	
	One Step Malaria P.f Test[b]	W37-C	2, 3, 4	
ICT INTERNATIONAL	ICT Malaria Combo Cassette Test	ML02	1, 3, 4	
	ICT Malaria Pf Cassette Test	ML01	1, 3	
	ICT Malaria Dual Test	ML03	3, 5	
InTec Products, Inc.	Advanced Quality™ One Step Malaria Pf Test	ITP11002TC1/TC40	1, 3	5
Humasis Co., Ltd.	Humasis Malaria Pf/Pan Antigen Test	AMAL-7025	4, 5	
J.Mitra & Co. Pvt. Ltd.	Advantage Pan Malaria Card	IR013025	1	5
	Advantage Mal Card	IR221025	1	5
	Advantage P.f Malaria Card	IR016025	1	5
Orchid Biomedical Systems	Paracheck® Pf Device - Rapid test for *P. falciparum* Malaria (Ver. 3)[c]	30301025	1, 3, 4	
	Paracheck® Pf Dipstick - Rapid test for *P. falciparum* Malaria (Ver.3)[c]	30302025	1, 3, 4	
Premier Medical Corporation Ltd.	First Response® Malaria Ag Combo (pLDH/HRP2)[d]	I16FRC	1, 2, 5	
	First Response Malaria Ag *P. falciparum* (HRP2) Card Test	I13FRC	1	5
SSA Diagnostics & Biotech Systems	diagnosticks- Malaria (Pf)Cassette WB	KMFC6001	2, 5	
Standard Diagnostics Inc.	SD BIOLINE Malaria Ag	05FK40	1, 3	
	SD BIOLINE Malaria Ag Pf/Pan	05FK60/05FK63	1, 3, 5	
	SD BIOLINE Malaria Antigen	05FK50/05FK53	1	5
Unimed International Inc.	FirstSign™ - ParaView (Pan+Pf) Malaria Test	2101 CB-25	2, 4	
Vision Biotech (Pty) Ltd / Orgenics (Alere Healthcare (Pty) Ltd subsidaries)	Malaria Rapid Combo/Clearview® Malaria Combo	VB11[e]	1, 3	
	Malaria Rapid Pf /Clearview ®Malaria Pf	VB01	1, 3, 5	
	Malaria Rapid Dual/Clearview® Malaria Dual Test Device	VB20[e]	1, 3, 5	
Zephyr Biomedical Systems	Malascan™ Device - Rapid test for Malaria Pf/Pan	50402025	1, 3	
	Parabank™ Device - Rapid test for Malaria Pan	50301025	1, 3	
	Parascreen™ Device -Rapid test for Malaria Pan/Pf	50310025	1, 3, 4, 5	
	Falcivax Rapid Test for Malaria Pv/Pf (device)	50300025	2, 4	

[a] Round 1 product name error: published - Malaria Pf (HRPII)/pv-LDH) Antigen Detection Test Device Code; corrected product name: Malaria Pf (HRPII/PAN-LDH) Antigen Detection Test Device Code. No change in product code.

[b] In round 2, product did not pass phase-1, therefore results do not feature in summary tables.

[c] Ver.3 was introduced after round 1

[d] Error in WHO malaria RDT product testing: round 1 report: product code (II6FRC30) should have been (I16FRC), as in round 2

[e] New company acquisition (Alere™), therefore change in product branding and catalogue numbers; VB011 to VB11 and VB020 to VB20. Manufacturer confirmed compliance with product definition.

Table S2: Malaria RDT phase-2 performance in rounds 2–5 against wild-type (clinical) samples containing *P. falciparum* (Pf) and *P. vivax* (Pv) at low (200) and high (2000–5000) parasite density (parasites/µL) and clean-negative samples

Product	Catalogue number	Manufacturer	Panel detection score[a]				False-positive rates (%)				Total false-positive rates[b] (%)	Invalid rate (%)[l]	Round
			200 parasites/µL		2000 or 5000 parasites/µL		200 parasites/µL		2000 or 5000 parasites/µL		Clean-negative samples		
							Pf samples	Pv samples	Pf samples	Pv samples			
			Pf samples[c]	Pv samples[d]	Pf samples[c]	Pv samples[d]	False-positive non-Pf infection[e]	False-positive Pf infection[f]	False-positive non-Pf infection[g]	False-positive Pf infection[h]	False-positive *Plasmodium* spp. Infection[i]		
Pf only													
ABON™ Malaria P.f. Rapid Test Device (Whole Blood)	IMA-402	ABON Biopharm (Hangzhou) Co. Ltd	32.7	NA	99.0	NA	NA	0.0	NA	0.0	0.4	0.0	4
Advanced Quality™ One Step Malaria Pf Test[j]	ITP11002TC1/ TC40	InTec Products, Inc.	53.0	NA	93.0	NA	NA	3.6	NA	5.7	7.7 (233)	0.4	5
Advantage P.f. Malaria Card[j]	IR016025	J. Mitra & Co. Pvt. Ltd.	89.0	NA	99.0	NA	NA	0.7	NA	0.0	0.0	0.0	5
BIOCREDIT Malaria pf(HRP II)	HR0100	RapiGen Inc.	99.0	NA	100.0	NA	NA	97.1	NA	95.59	99.1 (231)	0.5	4
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	Bionote,Inc.	85.9	NA	99.0	NA	NA	0.0	NA	1.4	2.0	0.1	3
CareStart™ Malaria HRP2 (Pf)[j]	G0141	Access Bio, Inc.	91.0	NA	100.0	NA	NA	0.0	NA	0.0	0.9	0.0	5
CareStart™ Malaria HRP2/pLDH Pf test	G0181	Access Bio, Inc.	98.0	NA	100.0	NA	NA	0.6	NA	1.3	3.0	0.0	2
Clearview® Malaria P.f.[j]	VB01	Vision Biotech (Pty) Ltd	83.8	NA	100.0	NA	NA	0.0	NA	0.0	0.0	0.0	3
Core™ Malaria Pf	MAL-190020	Core Diagnostics	97.0	NA	100.0	NA	NA	0.0	NA	0.0	1.0 (198)	0.3	3
diagnosticks- Malaria (Pf) Cassette WB	KMFC6001	SSA Diagnostics & Biotech Systems	88.0	NA	100.0	NA	NA	2.1	NA	1.4	0.9 (235)	0.3	5
diagnosticks- Malaria (Pf) Dipstick WB	KMFD6007	SSA Diagnostics & Biotech Systems	80.0	NA	99.0	NA	NA	2.5	NA	3.8	2.0	0.0	2
First Response® Malaria Ag *P. falciparum* (HRP2) Card Test[j]	I13FRC	Premier Medical Corporation Ltd.	95.0	NA	100.0	NA	NA	0.7	NA	0.0	0.4	0.0	5
FirstSign™ Malaria Pf	2100CB-25	Unimed International Inc.	94.9	NA	100.0	NA	NA	0.7	NA	1.47	2.2 (231)	0.2	4
HiSens Malaria Ag Pf HRP2 Card	HR3023	HBI Co., Ltd.	87.0	NA	100.0	NA	NA	0.0	NA	0.0	1.0	0.1	2
ICT Diagnostics Malaria P.f.[j]	ML01	ICT INTERNATIONAL	86.9	NA	98.0	NA	NA	0.0	NA	0.0	0.0	0.0	3
IMMUNOQUICK CONTACT *falciparum*	0519K25	Biosynex	81.8	NA	100.0	NA	NA	3.6 (139)	NA	1.4	4.0 (199)	0.3	3
IMMUNOQUICK® MALARIA *falciparum*[j]	0502_K25	Biosynex	72.0	NA	93.0	NA	NA	3.6	NA	4.3	5.1 (234)	0.2	5
IND ONE STEP MALARIA ANTIGEN P.f	535-11	IND Diagnostics Inc.	61.2	NA	99.0	NA	NA	2.2	NA	14.71	6.0	0.1	4
KHB® Malaria Ag P.f Rapid Test	KH-R-06-20	Shanghai Kehua Bio-engineering Co.,Ltd.	79.0	NA	91.8(98)	NA	NA	11.4	NA	12.9	10.6 (235)	0.7	5
Maleriscan ® Malaria P.f Antigen Test	MAT-PF-50	Bhat Bio-Tech India (Pte.) Ltd.	83.7	NA	98.0	NA	NA	1.5	NA	0.0	0.4	0.2	4
NanoSign Malaria Pf Ag	RMAF10	Bioland, Ltd	84.9	NA	100.0	NA	NA	0.0	NA	0.0	0.0	0.3	3
One Step Malaria P.F Test (Cassette)[j]	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	94.9	NA	99.0	NA	NA	0.0	NA	1.47	1.3	0.0	4
OnSight™ - Malaria Pf Test	511-25-DB	Amgenix International, Inc.	74.0	NA	99.0	NA	NA	8.1	NA	2.5	11.0	0.0	2
OnSite Pf Ag Rapid Test[j]	R0114C	CTK Biotech, Inc.	85.9	NA	100.0	NA	NA	0.7	NA	0.0	3.5	0.0	3
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Device (Ver.3)[j]	302030025	Orchid Biomedical Systems	95.9	NA	98.0	NA	NA	0.0	NA	0.0	1.3	0.0	4
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Dipstick (Ver.3)[j]	302040025	Orchid Biomedical Systems	70.4	NA	99.0	NA	NA	0.0	NA	0.0	0.9	0.0	4
ParaHIT® - f (Device)	55IC104-50	Span Diagnostics Ltd.	84.9	NA	100.0	NA	NA	0.0	NA	0.0	0.0	0.0	3
ParaHIT® -f (Dipstick)	55IC103-50	Span Diagnostics Ltd.	80.8	NA	99.0	NA	NA	0.0	NA	1.4	2.5	0.0	3
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH)[k]	05FK90	Standard Diagnostics Inc.	87.9	NA	100.0	NA	NA	0.0	NA	0.0	2.0	0.0	3
SD BIOLINE Malaria Ag Pf[j]	05FK50/05FK53	Standard Diagnostics, Inc.	95.0	NA	99.0	NA	NA	0.0	NA	2.9	0.0	0.0	5
Trusty™ Malaria Antigen P.f. test	A03-01-322	Artron Laboratories Inc.	88.8	NA	100.0	NA	NA	4.4 (135)	NA	2.94	5.2 (230)	0.7	4
Vision Malaria Pf[j]	VB01	Vision Biotech (Pty) Ltd	84.0	NA	100.0	NA	NA	2.1	NA	1.4	5.1 (235)	0.1	5
Wondfo One Step Malaria P.f Test[j]	W 37-C	Guangzhou Wondfo Biotech Co. Ltd.	89.8	NA	99.0	NA	NA	0.0	NA	0.0	0.4 (231)	0.2	4
Pf and pan													
ABON Malaria Pan/P.f. Rapid Test Device	IMA-B402	ABON Biopharm (Hangzhou) Co. Ltd.	69.7	0.0	99.0	62.9	0.0	0.0	0.0	0.0	0.0	0.0	3
ABON™ Plus Malaria *P.f/Pan* Rapid Test Device (Whole Blood)	IMA-T402	ABON Biopharm (Hangzhou) Co. Ltd	85.7	5.9	100.0	97.1	0.0	0.0	0.0	0.0	0.4	0.0	4
ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test	MAGC 25	LAB-CARE Diagnostics (India) PVT. LTD.	66.0	37.1	92.0	97.1	0.3	0.0 (139)	0.0 (199)	0.0	7.3 (234)	0.4	5
Advanced Quality™ Rapid Malaria Test (Pf/Pan)	ITP11005	InTec Products, Inc.	88.0	60.0	100.0	97.1	0.3 (389)	6.7 (134)	0.0 (197)	1.4	8.7 (231)	2.1	5
Advantage Mal Card[j]	IR221025	J. Mitra & Co. Pvt. Ltd.	30.0	94.3	94.0	97.1	1.5	0.7	0.5	0.0	0.4	0.0	5

Table S2 *(continued)*

Product	Catalogue number	Manufacturer	Panel detection score[a]				False-positive rates (%)				Total false-positive rates[b] (%)	Invalid rate (%)[l]	Round
			200 parasites/µL		2000 or 5000 parasites/µL		200 parasites/µL		2000 or 5000 parasites/µL		Clean-negative samples		
							Pf samples	Pv samples	Pf samples	Pv samples			
			Pf samples[c]	Pv samples[d]	Pf samples[c]	Pv samples[d]	False-positive non-Pf infection[e]	False-positive Pf infection[f]	False-positive non-Pf infection[g]	False-positive Pf infection[h]	False-positive *Plasmodium* spp. Infection[i]		
Advantage Malaria Pan + Pf Card	IR231025	J. Mitra & Co. Pvt. Ltd.	84.0	100.0	100.0	100.0	3.5	0.0	0.0	0.0 (69)	0.0	0.2	5
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device[k]	MFV-124F	AZOG, INC.	62.2	0.0	98.0	88.2	0.0 (390)	5.2	0.0	0.0	1.7 (231)	0.3	4
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN INC.	77.0	77.1	99.0	97.1	0.8	0.7	0.5 (198)	0.0	4.7	0.2	5
BIONOTE MALARIA P.f.& Pan Ag Rapid Test Kit	RG19-08	Bionote,Inc.	93.9	88.6	99.0	100.0	0.0	0.0	0.0	0.0	3.0 (199)	0.1	3
BioTracer™ Malaria Pf/PAN Rapid Card	17012	Bio Focus Co., Ltd.	77.0	77.1	94.0	100.0	0.5	0.7	2.0	0.0	0.4	0.0	5
CareStart™ Malaria/Pregnancy Combo (pLDH/HRP2/HCG)	G0221	Access Bio, Inc.	83.8	94.3	100.0	97.1	2.3	1.4 (139)	0.0 (194)	1.4	0.0	0.2	3
CareStart™ Malaria HRP2/pLDH (Pf/PAN) COMBO[j]	G0131	Access Bio, Inc.	90.0	94.3	100.0	100.0	1.5	0.7	0.0	0.0	0.4	0.0	5
CareStart™ Malaria pLDH 3 Line Test	G0121	Access Bio, Inc.	88.9	91.4	100.0	100.0	1.3	0.7	6.1	0.0	0.5	0.0	3
CareStart™ Malaria Screen	G0231	Access Bio, Inc.	86.9	88.6	100.0	100.0	1.8	2.1	0.0	0.0	2.5 (199)	0.1	3
Clearview® Malaria Combo[j]	VB11	Vision Biotech (Pty) Ltd	82.8	5.7	100.0	91.4	0.0	5.7	0.5	5.7	3.5	0.0	3
Clearview® Malaria Dual[j]	VB20	Orgenics Ltd.(IS)	89.0	60.0	99.0	85.7	0.3	12.1	0.5	7.1	12.7	0.0	5
Core™ Malaria Pan Pf	MAL-190024	Core Diagnostics Ltd.	99.0	26.5	100.0	29.4	0.0	33.8	0.0	42.7	32.2 (230)	0.3	4
diagnosticks MALARIA (Pan/Pf) Cassette	MPNFWBC 1007.4	SSA Diagnostics & Biotech Systems	98.0	51.4	100.0	97.1	0.0 (394)	0.0	0.0	0.0 (69)	2.5	0.3	3
DIAQUICK Malaria *P.f/Pan* Cassette	Z11200CE	DIALAB GmbH	90.0	82.9	100.0	97.1	0.3	2.9	0.0	1.5 (67)	2.1	0.2	5
EzDx™ Malaria Pan/Pf Rapid Test Detection kit[j]	RK MAL 001	Advy Chemical (Affiliate of Bharat Serums & Vaccines Ltd.)	83.0	80.0	100.0	100.0	0.3	0.7 (139)	0.0	0.0	1.3 (235)	0.3	5
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test[j]	I16FRC	Premier Medical Corporation Ltd.	85.0	74.3	100.0	100.0	0.3	0.0	0.0	0.0	0.0	0.0	5
FirstSign™ ParaView (Pan+Pf)[j]	2101CB-25	Unimed International Inc.	87.8	61.8	100.0	100.0	0.3	1.5	0.0	0.0	2.6	0.0	4
GenBody™Malaria Pf/Pan Ag	MALAG100	GenBody Inc.	84.0	54.3	100.0	97.1	0.0	0.0	0.0	0.0	0.0 (235)	0.2	5
Genedia® Malaria *P.f/Pan* Ag Rapid Test	20-0146-01	Green Cross Medical Science Corp. (Korea)	67.0	17.1	96.0	88.6	0.0	13.6	0.0	7.1	10.6	0.1	5
HiSens Malaria Ag P.f/P.v Card	HR2823	HBI Co., Ltd.	20.0	15.0	94.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0	2
HiSens Malaria Ag Pf/Pv (HRP2/pLDH) Card	HR2923	HBI Co., Ltd.	84.0	75.0	99.0	100.0	0.0	0.0	0.0	0.0	0.5	0.0	2
Humasis Malaria *P.f/Pan* Antigen Test[j]	AMAL-7025	Humasis, Co., Ltd.	90.0	91.4	100.0	97.1	0.5 (396)	0.0 (138)	0.0 (199)	1.4	0.9 (235)	0.7	5
ICT Malaria Dual Test [j]	ML03	ICT INTERNATIONAL	93.0	40.0	98.0	94.3	0.3	4.3	0.5	2.9	3.0	0.0	5
ICT MALARIA COMBO[j]	ML02	ICT INTERNATIONAL	76.5	5.9	99.0	88.2	0.5	0.7	0.0 (195)	1.5	0.4	0.1	4
IMMUNOQUICK CONTACT MALARIA +4	0525K25	Biosynex	75.8	17.1	98.0	94.3	1.8 (395)	5.1 (138)	0.0	0.0	2.0	0.3	3
IND ONE STEP MALARIA ANTIGEN *P.f/Pan* TEST	535-10	IND Diagnostics Inc.	94.9	61.8	100.0	85.3	0.0	2.2	0.0	5.9	1.3	0.0	4
Malaria Pan Test	MAL-W23N-001	Dima • Gesellschaft für Diagnostika mbH	54.6	0.0	97.0	48.6	2.8	15.7	0.0	17.1	44.0	0.0	3
Malaria Pf./Pan Antigen (MAL Pf/Pan) Test Kit	A03-18-322	Artron Laboratories Inc.	61.0	2.9	95.0	97.1	0.0 (398)	4.3	0.0 (199)	0.0	0.9	0.2	5
Malaria pf (HRP II) / (PAN-pLDH) Antigen Detection Test Device[j]	MFV-124R	AZOG, Inc.	95.0	0.0	100.0	94.3	0.0 (395)	7.9	8.1	0.0	5.5 (199)	0.3	3
Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device	1-13-101-1	United Biotech, Inc.	63.3	2.9	100.0	85.3	0.0	0.0 (135)	0.0	0.0	0.0	0.1	4
Malaria pf (pLDH) / PAN-pLDH Test Device [j]	MFV-124	AZOG, Inc.	41.0	8.6	97.0	45.7	22.5	47.9	1.5	35.7	81.3 (235)	0.1	5
Malaria Pf/ PAN	GM004	Genomix Molecular Diagnostics *Pvt.Ltd.*	39.8	2.9	94.9	97.1	0.3	0.7	0.0	0.0	0.0	0.0	4
Malaria Pf/Pan One Step Rapid Test	RT 20222	Zhejiang Orient Gene Biotech Co., Ltd.	89.0	91.4	100.0	100.0	0.0 (398)	0.7 (138)	0.0 (199)	0.0 (69)	0.4 (232)	1.0	5
Malascan™ Device - Rapid test for Malaria Pf/Pan[j]	50402025	Zephyr Biomedical Systems	82.8	57.1	97.0	100.0	1.0 (392)	0.7 (136)	1.0 (194)	0.0 (68)	1.0 (195)	1.9	3
MD Malaria Pf/Pan(pLDH) test	MDMALLDH001	Medical Diagnostech (Pty) Ltd	95.0	28.6	100.0	40.0	0.0	38.6	0.0	40.0	39.4	0.0	5
MeDiPro Malaria Ag HRP2/pLDH Combo	IR-0051K	Formosa Biomedical Technology Corp.	69.4	2.9	99.0	0.0	0.0 (391)	0.0	0.0	1.5	0.9	0.1	4
NanoSign Malaria pf/pan Ag 3.0[j]	RMAP10	Bioland Ltd.	92.9	97.1	100.0	100.0	0.8	0.0	0.0	0.0	0.4	0.0	4
NanoSign Malaria Pf/Pv Ag -	RMAD10	Bioland, Ltd	6.1	8.6	89.9	100.0	0.5	0.0 (139)	0.0	0.0	0.0	0.1	3
NG-Test MALARIA Pf/Pan (pLDH)	NG-MAL-W23-001	SARL NG Biotech, Z.A.	90.0	65.7	100.0	94.3	0.5 (399)	9.3	0.0	4.3	15.3	0.1	5

(continued)

Table S2: Malaria RDT phase-2 performance in rounds 2–5 against wild-type (clinical) samples containing *P. falciparum* (Pf) and *P. vivax* (Pv) at low (200) and high (2000–5000) parasite density (parasites/µL) and clean-negative samples *(continued)*

Product	Catalogue number	Manufacturer	Panel detection score[a]				False-positive rates (%)				Total false-positive rates[b] (%)	Invalid rate (%)[l]	Round
			200 parasites/µL		2000 or 5000 parasites/µL		200 parasites/µL		2000 or 5000 parasites/µL		Clean-negative samples		
			Pf samples[c]	Pv samples[d]	Pf samples[c]	Pv samples[d]	Pf samples	Pv samples	Pf samples	Pv samples			
							False-positive non-Pf infection[e]	False-positive Pf infection[f]	False-positive non-Pf infection[g]	False-positive Pf infection[h]	False-positive *Plasmodium* spp. Infection[i]		
One Step Malaria *P.f/Pan* Test[j]	W56-C	Guangzhou Wondfo Biotech Co. Ltd.	37.4	85.7	95.0	100.0	8.4 (383)	0.0 (137)	0.0 (194)	0.0 (68)	4.1 (195)	2.4	3
OnSite Pf/Pan Ag Rapid Test[j]	R0113C	CTK Biotech, Inc.	86.0	88.6	100.0	97.1	0.0 (399)	0.0	0.0	1.4	1.3	0.1	5
OptiMAL-IT	710024	Diamed - A Division of Bio-Rad	50.5	97.1	96.0	68.6	1.5	0.0	0.5	20.3 (69)	2.0 (198)	0.5	3
ParaHIT - Total Ver. 1.0 (Device)	55IC204-10	Span Diagnostics Ltd.	84.7	82.4	99.0	91.2	0.3	0.0	0.5	3.0 (67)	0.0	0.1	4
ParaHIT - Total Ver. 1.0 (Dipstick)	55IC203-10	Span Diagnostics Ltd.	76.5	61.8	100.0	94.1	0.8	0.0	0.0	1.5	0.0	0.0	4
ParaHIT® total (dipstick)	55IC201-10	Span Diagnostics Ltd	64.0	10.0	99.0	97.5	0.0	0.0	0.0	0.0	7.0	0.0	2
Parascreen® - Rapid test for Malaria Pan/Pf[j]	50310025	Zephyr Biomedicals	92.0	37.1	100.0	97.1	0.5	0.7	0.0 (199)	1.4	4.2	0.1	5
RightSign™ Malaria P.f./Pan Rapid Test Cassette	IMPN-C52	Hangzhou Biotest Biotech Co. Ltd.	74.0	40.0	94.0	88.6	2.0	2.9	0.5	5.7	14.0	0.0	5
SD BIOLINE Malaria Ag *P.f/Panj*	05FK60/05FK63	Standard Diagnostics Inc.	94.0	91.4	99.0	97.1	0.8	0.7	0.5	1.4	0.0	0.0	5
SD BIOLINE Malaria Ag Pf/ Pan	05FK66	Standard Diagnostics Inc.	90.8	94.1	100.0	100.0	1.0 (385)	0.0 (130)	0.0 (195)	0.0 (67)	1.3 (226)	2.8	4
SD BIOLINE Malaria Ag[j]	05FK40	Standard Diagnostics Inc.	16.2	97.1	93.9	100.0	0.8	0.0	0.0	0.0	0.0	0.0	3
Surestep™ Easy Malaria Pf/Pan Rapid Test Device	IMA-T402	ACON Biotech (Hangzhou) Co. Ltd.	83.8	0.0	100.0	100.0	0.0	0.0	0.0	0.0	1.0	0.0	3
Vikia® Malaria Ag Pf/Pan	412499	IMACCESS S.A.S	86.0	5.7	97.0	94.3	0.0	0.7 (139)	0.5 (199)	0.0 (69)	1.3 (235)	0.3	5
Pf and Pv/Pvom													
Advanced Quality™ One Step Malaria P.f/P.v Tri-Line Test	ITP11003 TC40	InTec Products, Inc.	86.9	0.0	100.0	5.7	15.7 (395)	5.7	8.1 (197)	4.3	18.5	0.2	3
Advantage Malaria Card	IR211025	J. Mitra & Co. Pvt. Ltd.	77.8	31.4	99.0	100.0	0.5	0.7	0.0	0.0	0.0	0.0	3
ASAN Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	81.0	34.3	99.0	100.0	16.5	0.0	85.5	0.0	0.4 (235)	0.2	5
BIONOTE MALARIA P.f.& P.v. Ag Rapid Test Kit	RG19-12	Bionote,Inc.	92.9	97.1	98.0	100.0	0.3	0.7	1.5 (197)	0.0	4.0	0.0	3
CareStart™ Malaria HRP2/pLDH (Pf/Pv) COMBO[j]	G0161	Access Bio, Inc.	90.8	94.1	100.0	100.0	0.3	0.0	1.0	1.5	0.0	0.0	4
CareStart™ Malaria HRP2/pLDH (Pf/VOM) COMBO[j]	G0171	Access Bio, Inc.	89.8	91.2	100.0	100.0	0.3	0.7	0.5	2.9	0.0	0.0	4
Core™ Malaria Pv/Pf	MAL-190022	Core Diagnostics	98.0	60.0	100.0	97.1	0.3	0.0	0.0	0.0	4.0	0.1	3
diagnosticks- Malaria (Pv/Pf) Cassette	KMVFC6002	SSA Diagnostics & Biotech Systems	91.0	45.0	99.0	100.0	0.3 (399)	0.6	0.0	0.0	2.0	0.1	2
FalciVax™ - Rapid test for Malaria Pv/Pf[j]	50300025	Zephyr Biomedicals	98.0	88.2	100.0	100.0	0.8	2.9	0.0	2.9	7.3	0.0	4
HiSens Malaria Ag P.f/P.v Combo Card	HR3123	HBI Co., Ltd.	89.8	79.4	100.0	94.1	0.3 (391)	0.0	0.5	0.0	0.4	0.1	4
HiSens Malaria Ag *P.f/VOM* Combo Card	HR3323	HBI Co., Ltd.	89.8	76.5	100.0	91.2	0.0	0.0	0.5	0.0	0.0	0.0	4
Humasis Malaria P.f/P.v Antigen Test	AMFV-7025	Humasis, Co., Ltd.	92.9	100.0	100.0	100.0	0.5	0.7	0.5	1.5	1.3	0.0	4
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	1-13-101-3	United Biotech, Inc.	60.2	0.0	92.9	26.5	0.5	0.0 (135)	3.1 (195)	1.5	0.0 (230)	0.5	4
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	MFV-124V	AZOG, Inc.	79.8	0.0	100.0	20.0	0.0	1.4	0.0	0.0	0.0 (199)	0.1	3
Malaria Pf (HRPII)/ PV (PLDH) Antigen Detection Test Device	GM006	Genomix Molecular Diagnostics Pvt. Ltd.	85.0	74.3	97.0	94.3	1.5 (391)	6.5 (138)	3.6 (195)	2.9	0.9 (232)	2.5	5
Malaria Pf/Pv	GM002	Genomix Molecular Diagnostics *Pvt.Ltd.*	40.8	0.0	94.9	5.9	0.8	0.7	0.5	0.0	0.9	0.0	4
Maleriscan® Malaria Pf/PAN (Pv, Pm, Po) 3 Line Antigen Test[j]	MAT-PF/PAN-50	Bhat Bio-Tech India (P) Ltd.	84.0	62.9	100.0	100.0	27.3 (399)	5.8 (139)	87.4 (199)	4.3 (69)	3.0 (232)	0.7	5
Maleriscan® Malaria Pf/Pv	MAT-50	Bhat Bio-Tech India (P) Ltd	52.0	0.0	97.0	60.0	1.8 (399)	2.5	32.5	2.5 (79)	1.5 (199)	0.4	2
Medisensor Malaria HRP2/pLDH (Pf/Pv) COMBO	M161	Medisensor, Inc.	90.8	94.1	100.0	100.0	0.3	0.0	1.0	1.5	0.0	0.0	4
Medisensor Malaria HRP2/pLDH (Pf/VOM) COMBO	M171	Medisensor, Inc.	89.8	91.2	100.0	100.0	0.3	0.7	0.5	2.9	0.0	0.0	4
One Step Malaria P.F/P.V Test (Cassette)[j]	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	92.0	100.0	100.0	100.0	21.5	53.6	9.0	34.3	77.1	0.0	5
OnSight™ - ParaQuick-2 (Pv,Pf) Malaria Test	537-25-DB	Amgenix International, Inc.	92.0	37.5	100.0	100.0	0.5	1.9	0.0	0.0	3.5	0.1	2
OnSite Pf/Pv Ag Rapid Test[j]	R0112C	CTK Biotech, Inc.	79.6	100.0	100.0	100.0	1.5	0.0	2.0	0.0	1.3	0.0	4
ParaHIT®fV Rapid test for *P. falciparum* and *P. vivax* Malaria - Device	55IC402-50	Span Diagnostics Ltd.	63.0	37.1	91.0	85.7	2.0 (399)	5.7	0.5	2.9	6.4	0.1	5
RAPID 1-2-3® HEMA CASSETTE MALARIA PF/PV TEST	MAL-PFV-CAS/25(100)	Hema Diagnostic Systems, LLC	92.9	79.4	100.0	100.0	0.0	0.7	0.0	1.5	4.3	0.0	4

Table S2 *(continued)*

Product	Catalogue number	Manufacturer	Panel detection score[a]				False-positive rates (%)				Total false-positive rates[b] (%)	Invalid rate (%)[l]	Round
			200 parasites/µL		2000 or 5000 parasites/µL		200 parasites/µL		2000 or 5000 parasites/µL		Clean-negative samples		
							Pf samples	Pv samples	Pf samples	Pv samples			
			Pf samples[c]	Pv samples[d]	Pf samples[c]	Pv samples[d]	False-positive non-Pf infection[e]	False-positive Pf infection[f]	False-positive non-Pf infection[g]	False-positive Pf infection[h]	False-positive *Plasmodium* spp. Infection[i]		
SD BIOLINE Malaria Ag Pf/ Pf/ Pv[k]	05FK100	Standard Diagnostics Inc.	96.9	97.1	100.0	100.0	0.3	0.0	0.5	0.0	2.2	0.0	4
SD BIOLINE Malaria Ag Pf/Pv	05FK80/05FK83	Standard Diagnostics, Inc.	96.0	95.0	100.0	100.0	0.0	0.0 (159)	0.0 (199)	0.0	3.5	0.2	2
Trusty™ Malaria Antigen P.f./p.v. test	A03-12-322	Artron Laboratories Inc.	88.8	38.2	99.0	100.0	13.3	27.4 (135)	16.0 (194)	19.4 (67)	32.0 (231)	0.5	4
Wondfo® One Step Malaria P.f/P.v Whole Blood Test	W056-C	Guangzhou Wondfo Biotech Co. Ltd.	87.0	28.6	98.0	97.1	1.5 (399)	2.9	1.5	2.9	2.1	0.1	5
Pf, Pv and pan													
Core™ Malaria Pan/Pv/Pf	MAL-190026	Core Diagnostics	92.9	11.4	99.0	94.3	0.3 (391)	0.0 (137)	0.0 (197)	1.4	3.5 (198)	1.0	3
diagnosticks MALARIA (Pan/Pv/Pf) Cassette	MPNVFC1007.5	SSA Diagnostics & Biotech Systems	93.9	11.4	99.0	94.3	0.0 (389)	0.0 (139)	0.0 (196)	2.9 (69)	4.0 (199)	1.1	3
FirstSign™ - ParaView-3 (Pan+Pv+Pf) Malaria Test	2103 CB-25	Unimed International Inc.	89.0	45.0	100.0	100.0	0.0 (399)	2.5	0.0	0.0	24.5	0.1	2
Paramax-3 Rapid Test for Malaria Pan/Pv/Pf (device)	50320025	Zephyr Biomedicals	93.0	45.0	100.0	100.0	0.0 (396)	0.0 (159)	0.0 (199)	0.0	37.0 (198)	0.7	2
Pan only													
Advantage Pan Malaria Card[j]	IR013025	J. Mitra & Co. Pvt. Ltd.	77.0	100.0	98.0	100.0	NA	NA	NA	NA	0.4	0.0	5
AZOG hCG Malaria Detection Test Device	MPT-124	AZOG, INC.	61.2	0	99	55.9	NA	NA	NA	NA	2.2	0.2	4
CareStart™ Malaria pLDH (PAN)[j]	G0111	Access Bio, Inc.	84.0	88.6	99.0	97.1	NA	NA	NA	NA	0.0	0.0	5
Clearview® Malaria pLDH[j]	70884025	Orgenics Ltd. (Inverness Medical Innovations)	81.8	85.7	99.0	100.0	NA	NA	NA	NA	13.5	0.5	3
diagnosticks MALARIA (Pan) Cassette	MPNWBC1007.3	SSA Diagnostics & Biotech Systems	16.2	54.3	92.9	100.0	NA	NA	NA	NA	0.0	0.3	3
First Response® Malaria Ag pLDH	I12FRC30	Premier Medical Corporation Ltd.	31.0	92.5	98.0	100.0	NA	NA	NA	NA	0.0	0.0	2
FirstSign™ - PanCheck (Pan) Malaria Test	2104 CB-25	Unimed International Inc.	25.0	82.5	87.0	100.0	NA	NA	NA	NA	2.5	0.2	2
OnSight™ - PanScreen (Pan) Malaria Test	539-25-DB	Amgenix International, Inc.	22.0	77.5	96.0	100.0	NA	NA	NA	NA	2.5	0.2	2
Parabank™ Device - Rapid test for Malaria Pan[j]	50301025	Zephyr Biomedical Systems	17.2	62.9	90.9	100.0	NA	NA	NA	NA	0.5	0.2	3
Pv only													
SD BIOLINE Malaria Ag Pv	05FK70	Standard Diagnostics, Inc.	NA	92.5	NA	100.0	0.3	NA	1.0	NA	1.0	0.0	2

NA, not applicable

Pf, *Plasmodium falciparum* Pv, *Plasmodium vivax* pan, *Plasmodium* species
Pvom, *Plasmodium vivax, ovale* and *malariae*

[a] A sample is considered detected only if all RDTs from both lots read by the first technician, at minimum specified reading time, are positive

[b] The total number of times a positive result for malaria was generated when it should not have been

[c] Round 1, n=79; round 2, n=100; round 3, n=99; round 4, n=98; round 5, n=100

[d] Round 1, n=20; round 2, n=40; round 3, n=35; round 4, n=34; round 5, n=35

[e] For combination tests, pan or Pv line, only, positive indicates a false-positive non *P. falciparum* infection (round 1 n=316; round 2, n=400; round 3, n=396; round 4, n=392; round 5, n=400)

[f] Pf line positive indicates a false-positive *P. falciparum* infection (round 1, n=80; round 2, n=160; round 3, n=140; round 4, n=136; round 5, n=140)

[g] For combination tests, pan or Pv line, only, positive indicates a false-positive non-*P. falciparum* infection (round 1, n=158; round 2, n=200; round 3, n=198; round 4, n=196; round 5, n=200)

[h] Pf line positive indicates a false-positive *P. falciparum* infection (round 1, n=40; round 2, n=80, round 3, n=70; round 4, n=68; round 5, n=70)

[i] Round 1, n=168; round 2, n=200; round 3, n=200; round 4, n=232 round 5, n=236

[j] Product resubmission, results from most recent round of testing replace previous results. Refer to Table S1.

[k] PDS presented in the table is based on a positive pf test line (either pf-HRP2 or pf-pLDH). For test line-specific results refer to the tables and annexes in the full reports.

[l] Round 1, n=954; round 2, n=1240; round 3, n=1204; round 4, n=1192; Round 5, n=1214

Performance measure	Recommended WHO procurement criteria
Panel detection score for Pf and Pv 200/µL samples	≥ 75%
False-positive rates against clean-negatives	< 10%
Invalid rate	< 5% of tests conducted

Table S3: Malaria RDT rounds 2—5 heat stability results on a cultured *P. falciparum* sample at low (200) and high (2000) parasite density (parasites/µL). Positivity rate at baseline and after 60 days' incubation at 35 °C and 45 °C

Product	Catalogue number	Manufacturer	Percentage positive test results for *P. falciparum* (Pf line)			Percentage positive test results for *P. falciparum* (Pf line)			Percentage positive test results for *P. falciparum* (pan line)			Percentage positive test results for *P. falciparum* (pan line)			Round
			200 parasites/µL			2000 parasites/µL			200 parasites/µL			2000 parasites/µL			
			Baseline	35 °C	45 °C	Baseline	35 °C	45 °C	Baseline	35 °C	45 °C	Baseline	35 °C	45 °C	
			Number of tests positive			Number of tests positive			Number of tests positive			Number of tests positive			
			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			
Pf only															
ABON™ Malaria P.f. Rapid Test Device (Whole Blood)	IMA-402	ABON Biopharm (Hangzhou) Co. Ltd	15.0	15.0	17.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
Advanced Quality™ One Step Malaria Pf Test[a]	ITP11002TC1/ TC40	InTec Products, Inc.	93.3	96.7	90.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	5
Advantage P.f. Malaria Card[a]	IR016025	J. Mitra & Co. Pvt. Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	5
BIOCREDIT Malaria pf(HRP II)	HR0100	RapiGen Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	Bionote,Inc.	100.0	100.0	86.7	100.0	90.0	80.0	NA	NA	NA	NA	NA	NA	3
CareStart™ Malaria HRP2 (Pf)[a]	G0141	Access Bio, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	5
CareStart™ Malaria HRP2/pLDH Pf test	G0181	Access Bio, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	2
Clearview® Malaria P.f.[a]	VB01	Vision Biotech (Pty) Ltd	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	3
Core™ Malaria Pf	MAL-190020	Core Diagnostics	100.0	100.0	96.7	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	3
diagnosticks- Malaria (Pf) Cassette WB[a]	KMFC6001	SSA Diagnostics & Biotech Systems	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	5
diagnosticks- Malaria (Pf) Dipstick WB	KMFD6007	SSA Diagnostics & Biotech Systems	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	2
First Response® Malaria Ag *P. falciparum* (HRP2) Card Test[a]	I13FRC	Premier Medical Corporation Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	5
FirstSign™ Malaria Pf	2100CB-25	Unimed International Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
HiSens Malaria Ag Pf HRP2 Card	HR3023	HBI Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	2
ICT Diagnostics Malaria P.f.[a]	ML01	ICT International	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	3
IMMUNOQUICK CONTACT *falciparum*	0519K25	Biosynex	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	3
IMMUNOQUICK® MALARIA *falciparum*[a]	0502_K25	Biosynex	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	5
IND ONE STEP MALARIA ANTIGEN P.f	535-11	IND Diagnostics Inc.	100.0	100.0	86.7	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
KHB® Malaria Ag P.f Rapid Test	KH-R-06-20	Shanghai Kehua Bio-engineering Co.,Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	5
Maleriscan ® Malaria P.f Antigen Test	MAT-PF-50	Bhat Bio-Tech India (Pte.) Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
NanoSign Malaria Pf Ag	RMAF10	Bioland, Ltd	96.7	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	3
One Step Malaria P.F Test (Cassette)[a]	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
OnSight™ - Malaria Pf Test	511-25-DB	Amgenix International, Inc.	100.0	95.0	90.0	100.0	100.0	65.0	NA	NA	NA	NA	NA	NA	2
OnSite Pf Ag Rapid Test[a]	R0114C	CTK Biotech, Inc.	96.7	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	3
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Device (Ver.3)[j]	302030025	Orchid Biomedical Systems	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Dipstick (Ver.3)[j]	302040025	Orchid Biomedical Systems	100.0	96.7	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
ParaHIT® - f (Device)	55IC104-50	Span Diagnostics Ltd.	100.0	96.7	100.0	100.0	100.0	90.0	NA	NA	NA	NA	NA	NA	3
ParaHIT® -f (Dipstick)	55IC103-50	Span Diagnostics Ltd.	100.0	100.0	56.7	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	3
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH)[b]	05FK90	Standard Diagnostics Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	3
SD BIOLINE Malaria Ag Pf[a]	05FK50/05FK53	Standard Diagnostics, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	5
Trusty™ Malaria Antigen P.f. test	A03-01-322	Artron Laboratories Inc.	100.0	100.0	56.7	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
Vision Malaria Pf	VB01	Vision Biotech (Pty) Ltd	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	5
Wondfo One Step Malaria P.f Test[a]	W 37-C	Guangzhou Wondfo Biotech Co. Ltd.	100.0	96.7	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
Pf and pan															
ABON Malaria Pan/P.f. Rapid Test Device	IMA-B402	ABON Biopharm (Hangzhou) Co. Ltd.	100.0	80.0	90.0	100.0	100.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0	3
ABON™ Plus Malaria *P.f/Pan* Rapid Test Device (Whole Blood)	IMA-T402	ABON Biopharm (Hangzhou) Co. Ltd	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0	
ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test	MAGC 25	LAB-CARE Diagnostics (India) PVT. LTD.	83.3	73.3	10.0	100.0	100.0	100.0	3.3	10.0	0.0	70.0	90.0	30.0	5
Advanced Quality™ Rapid Malaria Test (Pf/Pan)	ITP11005	InTec Products, Inc.	86.7	96.7	100.0	100.0	100.0	100.0	0.0	0.0	0.0	70.0	100.0	80.0	5
Advantage Mal Card[a]	IR221025	J. Mitra & Co. Pvt. Ltd.	0.0	0.0	0.0	100.0	100.0	100.0	0.0	0.0	0.0	70.0	100.0	80.0	5

Table S3 *(continued)*

Product	Catalogue number	Manufacturer	Percentage positive test results for *P. falciparum* (Pf line)			Percentage positive test results for *P. falciparum* (Pf line)			Percentage positive test results for *P. falciparum* (pan line)			Percentage positive test results for *P. falciparum* (pan line)			Round
			200 parasites/µL			2000 parasites/µL			200 parasites/µL			2000 parasites/µL			
			Baseline	35 °C	45 °C	Baseline	35 °C	45 °C	Baseline	35 °C	45 °C	Baseline	35 °C	45 °C	
			Number of tests positive			Number of tests positive			Number of tests positive			Number of tests positive			
			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			
Advantage Malaria Pan + Pf Card	IR231025	J. Mitra & Co. Pvt. Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	80.0	93.3	26.7	100.0	100.0	100.0	5
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device[b]	MFV-124F	AZOG, INC.	96.7	96.7	100.0	100.0	100.0	100.0	3.3	0.0	0.0	20.0	0.0	0.0	4
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN INC.	100.0	100.0	96.7	90.0	100.0	100.0	0.0	53.3	0.0	90.0	100.0	100.0	5
BIONOTE MALARIA P.f.& Pan Ag Rapid Test Kit	RG19-08	Bionote,Inc.	100.0	100.0	96.7	100.0	100.0	100.0	0.0	0.0	0.0	100.0	100.0	90.0	3
BioTracer™ Malaria Pf/PAN Rapid Card	17012	Bio Focus Co., Ltd.	100.0	96.7	90.0	100.0	100.0	100.0	0.0	0.0	66.7	100.0	100.0	100.0	5
CareStart™ Malaria/Pregnancy Combo (pLDH/HRP2/HCG)	G0221	Access Bio Inc	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	3
CareStart™ Malaria HRP2/pLDH (Pf/PAN) COMBO[a]	G0131	Access Bio, Inc.	100.0	100.0	96.7	100.0	100.0	100.0	93.3	86.7	53.3	100.0	100.0	100.0	5
CareStart™ Malaria pLDH 3 Line Test	G0121	Access Bio, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	3
CareStart™ Malaria Screen	G0231	Access Bio, Inc.	100.0	100.0	93.3	100.0	100.0	100.0	100.0	100.0	93.3	100.0	100.0	100.0	3
Clearview® Malaria Comboa	VB11	Vision Biotech (Pty) Ltd	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	0.0	90.0	20.0	0.0	3
Clearview® Malaria Dual	VB20	Orgenics Ltd.(IS)	100.0	100.0	100.0	100.0	100.0	100.0	0.0	10.0	3.3	90.0	90.0	100.0	5
Core™ Malaria Pan Pf	MAL-190024	Core Diagnostics Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	26.7	80.0	83.3	100.0	100.0	100.0	4
diagnosticks MALARIA (Pan/Pf) Cassette	MPNFWBC 1007.4	SSA Diagnostics & Biotech Systems	100.0	100.0	96.7	100.0	100.0	100.0	0.0	0.0	0.0	100.0	90.0	90.0	3
DIAQUICK Malaria *P.f/Pan* Cassette	Z11200CE	DIALAB GmbH	100.0	100.0	96.7	100.0	100.0	100.0	0.0	0.0	0.0	100.0	100.0	80.0	5
EzDx™ Malaria Pan/Pf Rapid Test Detection kit[a]	RK MAL 001	Advy Chemical (Affiliate of Bharat Serums & Vaccines Ltd.)	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	3.3	100.0	100.0	100.0	5
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test[a]	I16FRC	Premier Medical Corporation Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	0.0	10.0	0.0	100.0	100.0	100.0	5
FirstSign™ ParaView (Pan+Pf)[a]	2101CB-25	Unimed International Inc.	96.7	100.0	100.0	100.0	100.0	100.0	0.0	0.0	13.3	100.0	100.0	100.0	4
GenBody™Malaria Pf/Pan Ag	MALAG100	GenBody Inc.	100.0	100.0	93.3	100.0	100.0	100.0	0.0	0.0	0.0	50.0	100.0	10.0	5
Genedia® Malaria *P.f/Pan* Ag Rapid Test	20-0146-01	Green Cross Medical Science Corp. (Korea)	100.0	100.0	43.3	100.0	100.0	100.0	3.3	0.0	13.3	0.0	0.0	0.0	5
HiSens Malaria Ag P.f/P.v Card	HR2823	HBI Co., Ltd.	35.0	0.0	5.0	100.0	100.0	100.0	0.0	0.0	0.0	35.0	0.0	0.0	2
HiSens Malaria Ag Pf/Pv (HRP2/pLDH) Card	HR2923	HBI Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	95.0	100.0	100.0	100.0	2
Humasis Malaria *P.f/Pan* Antigen Test[j]	AMAL-7025	Humasis, Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	0.0	100.0	100.0	100.0	5
ICT Malaria Dual Test[a]	ML03	ICT International	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	0.0	90.0	90.0	90.0	5
ICT MALARIA COMBO[a]	ML02	ICT International	96.7	96.7	93.3	100.0	100.0	100.0	3.3	20.0	13.3	100.0	50.0	70.0	4
IMMUNOQUICK CONTACT MALARIA +4	0525K25	Biosynex	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	0.0	50.0	50.0	100.0	3
IND ONE STEP MALARIA ANTIGEN *P.f/Pan* TEST	535-10	IND Diagnostics Inc.	100.0	100.0	100.0	100.0	100.0	100.0	20.0	3.3	33.3	100.0	100.0	100.0	4
Malaria Pan Test	MAL-W23N-001	Dima • Gesellschaft für Diagnostika mbH	60.0	33.3	23.3	100.0	100.0	90.0	13.3	53.3	40.0	10.0	60.0	40.0	3
Malaria Pf./Pan Antigen (MAL Pf/Pan) Test Kit	A03-18-322	Artron Laboratories Inc.	10.0	6.7	0.0	100.0	100.0	100.0	10.0	3.3	0.0	100.0	100.0	90.0	5
Malaria pf (HRP II) / (PAN-pLDH) Antigen Detection Test Device[a]	MFV-124R	AZOG, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0	3
Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device	1-13-101-1	United Biotech, Inc.	100.0	96.7	96.7	100.0	100.0	100.0	16.6	0.0	0.0	90.0	40.0	50.0	4
Malaria pf (pLDH) / PAN-pLDH Test Device a	MFV-124	AZOG, Inc.	46.7	56.7	66.7	100.0	100.0	100.0	13.3	93.3	100.0	60.0	100.0	100.0	5
Malaria Pf/ PAN	GM004	Genomix Molecular Diagnostics *Pvt.Ltd.*	56.7	23.3	26.7	100.0	100.0	100.0	0.0	0.0	0.0	60.0	90.0	50.0	4
Malaria Pf/Pan One Step Rapid Test	RT 20222	Zhejiang Orient Gene Biotech Co., Ltd.	100.0	100.0	96.7	100.0	90.0	100.0	0.0	0.0	0.0	100.0	90.0	100.0	5
Malascan™ Device - Rapid test for Malaria Pf/Pan[a]	50402025	Zephyr Biomedical Systems	96.7	100.0	96.7	100.0	100.0	100.0	0.0	0.0	6.7	100.0	100.0	100.0	3
MD Malaria Pf/Pan(pLDH) test	MDMALLDH001	Medical Diagnostech (Pty) Ltd	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	0.0	100.0	100.0	100.0	5
MeDiPro Malaria Ag HRP2/pLDH Combo	IR-0051K	Formosa Biomedical Technology Corp.	100.0	96.7	96.7	100.0	100.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0	4
NanoSign Malaria pf/pan Ag 3.0[a]	RMAP10	Bioland Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	0.0	100.0	100.0	100.0	4
NanoSign Malaria Pf/Pv Ag	RMAD10	Bioland, Ltd	0.0	0.0	0.0	20.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	3
NG-Test MALARIA Pf/Pan (pLDH)	NG-MAL-W23-001	SARL NG Biotech, Z.A.	100.0	100.0	100.0	100.0	100.0	100.0	0.0	6.7	0.0	100.0	100.0	100.0	5
One Step Malaria *P.f/Pan* Test[a]	W56-C	Guangzhou Wondfo Biotech Co. Ltd.	46.7	13.3	26.7	100.0	100.0	100.0	0.0	36.7	73.3	70.0	80.0	100.0	3

(continued)

Table S3: Malaria RDT rounds 2—5 heat stability results on a cultured *P. falciparum* sample at low (200) and high (2000) parasite density (parasites/µL). Positivity rate at baseline and after 60 days' incubation at 35 °C and 45 °C *(continued)*

Product	Catalogue number	Manufacturer	Percentage positive test results for *P. falciparum* (Pf line)			Percentage positive test results for *P. falciparum* (Pf line)			Percentage positive test results for *P. falciparum* (pan line)			Percentage positive test results for *P. falciparum* (pan line)			Round
			200 parasites/µL			2000 parasites/µL			200 parasites/µL			2000 parasites/µL			
			Baseline	35 °C	45 °C	Baseline	35 °C	45 °C	Baseline	35 °C	45 °C	Baseline	35 °C	45 °C	
			Number of tests positive			Number of tests positive			Number of tests positive			Number of tests positive			
			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			
OnSite Pf/Pan Ag Rapid Test[a]	R0113C	CTK Biotech, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	3.3	90.0	100.0	100.0	5
OptiMAL-IT	710024	Diamed - A Division of Bio-Rad	0.0	0.0	0.0	100.0	90.0	0.0	0.0	0.0	0.0	100.0	90.0	0.0	3
ParaHIT - Total Ver. 1.0 (Device)	55IC204-10	Span Diagnostics Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	0.0	100.0	100.0	100.0	4
ParaHIT - Total Ver. 1.0 (Dipstick)	55IC203-10	Span Diagnostics Ltd.	100.0	93.3	46.7	100.0	100.0	60.0	50.0	0.0	0.0	100.0	90.0	0.0	4
ParaHIT® total (dipstick)	55IC201-10	Span Diagnostics Ltd	55.0	85.0	55.0	100.0	100.0	95.0	10.0	0.0	0.0	50.0	45.0	70.0	2
Parascreen® - Rapid test for Malaria Pan/Pf[a]	50310025	Zephyr Biomedicals	100.0	100.0	100.0	100.0	100.0	100.0	10.0	3.3	13.3	100.0	100.0	100.0	5
RightSign™ Malaria P.f./Pan Rapid Test Cassette	IMPN-C52	Hangzhou Biotest Biotech Co. Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	0.0	20.0	100.0	100.0	60.0	100.0	5
SD BIOLINE Malaria Ag *P.f/Pana*	05FK60/05FK63	Standard Diagnostics Inc.	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	0.0	100.0	100.0	100.0	5
SD BIOLINE Malaria Ag Pf/ Pan	05FK66	Standard Diagnostics Inc.	96.7	96.7	100.0	90.0	100.0	100.0	16.6	10.0	0.0	90.0	100.0	100.0	4
SD BIOLINE Malaria Ag[a]	05FK40	Standard Diagnostics Inc.	0.0	0.0	0.0	100.0	80.0	90.0	0.0	0.0	0.0	80.0	20.0	90.0	3
Surestep™ Easy Malaria Pf/Pan Rapid Test Device	IMA-T402	ACON Biotech (Hangzhou) Co. Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0	3
Vikia® Malaria Ag Pf/Pan	412499	IMACCESS S.A.S	100.0	96.7	96.7	100.0	100.0	100.0	0.0	0.0	0.0	60.0	60.0	0.0	5
Pf and Pv/Pvom															
Advanced Quality™ One Step Malaria P.f/P.v Tri-Line Test	ITP11003 TC40	InTec Products, Inc.	96.7	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	3
Advantage Malaria Card	IR211025	J. Mitra & Co. Pvt. Ltd.	100.0	96.7	96.7	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	3
ASAN Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	100.0	96.7	63.3	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	5
BIONOTE MALARIA P.f.& P.v. Ag Rapid Test Kit	RG19-12	Bionote,Inc.	100.0	96.7	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	3
CareStart™ Malaria HRP2/pLDH (Pf/Pv) COMBO[a]	G0161	Access Bio, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
CareStart™ Malaria HRP2/pLDH (Pf/VOM) COMBO[a]	G0171	Access Bio, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
Core™ Malaria Pv/Pf	MAL-190022	Core Diagnostics	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	3
diagnosticks- Malaria (Pv/Pf) Cassette	KMVFC6002	SSA Diagnostics & Biotech Systems	100.0	95.0	95.0	100.0	100.0	95.0	NA	NA	NA	NA	NA	NA	2
FalciVax™ - Rapid test for Malaria Pv/Pf[a]	50300025	Zephyr Biomedicals	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
HiSens Malaria Ag P.f/P.v Combo Card	HR3123	HBI Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
HiSens Malaria Ag *P.f/VOM* Combo Card	HR3323	HBI Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
Humasis Malaria P.f/P.v Antigen Test	AMFV-7025	Humasis, Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	1-13-101-3	United Biotech, Inc.	100.0	100.0	100.0	90.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	MFV-124V	AZOG, Inc.	100.0	100.0	96.7	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	3
Malaria Pf (HRPII)/ PV (PLDH) Antigen Detection Test Device	GM006	Genomix Molecular Diagnostics Pvt. Ltd.	83.3	90.0	83.3	100.0	90.0	70.0	NA	NA	NA	NA	NA	NA	5
Malaria Pf/Pv	GM002	Genomix Molecular Diagnostics *Pvt.Ltd.*	40.0	33.3	40.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
Maleriscan® Malaria Pf/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	Bhat Bio-Tech India (P) Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	5
Maleriscan® Malaria Pf/Pv	MAT-50	Bhat Bio-Tech India (P) Ltd	100.0	60.0	30.0	100.0	90.0	95.0	NA	NA	NA	NA	NA	NA	2
Medisensor Malaria HRP2/pLDH (Pf/Pv) COMBO	M161	Medisensor, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
Medisensor Malaria HRP2/pLDH (Pf/VOM) COMBO	M171	Medisensor, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
One Step Malaria P.F/P.V Test (Cassette)[a]	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	5
OnSight™ - ParaQuick-2 (Pv,Pf) Malaria Test	537-25-DB	Amgenix International, Inc.	100.0	100.0	100.0	100.0	100.0	85.0	NA	NA	NA	NA	NA	NA	2
OnSite Pf/Pv Ag Rapid Test[a]	R0112C	CTK Biotech, Inc.	100.0	100.0	90.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
ParaHIT®fV Rapid test for *P. falciparum* and *P. vivax* Malaria - Device	55IC402-50	Span Diagnostics Ltd.	100.0	96.7	96.7	100.0	100.0	90.0	NA	NA	NA	NA	NA	NA	5
RAPID 1-2-3® HEMA CASSETTE MALARIA PF/PV TEST	MAL-PFV-CAS/25(100)	Hema Diagnostic Systems, LLC	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
SD BIOLINE Malaria Ag Pf/ Pf/ Pv[b]	05FK100	Standard Diagnostics Inc.	100.0	100.0	96.7	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
SD BIOLINE Malaria Ag Pf/Pv	05FK80/05FK83	Standard Diagnostics, Inc.	100.0	100.0	100.0	100.0	100.0	95.0	NA	NA	NA	NA	NA	NA	2
Trusty™ Malaria Antigen P.f./p.v. test	A03-12-322	Artron Laboratories Inc.	100.0	100.0	36.7	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
Wondfo® One Step Malaria P.f/P.v Whole Blood Test	W056-C	Guangzhou Wondfo Biotech Co. Ltd.	100.0	96.7	93.3	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	5

Table S3 *(continued)*

Product	Catalogue number	Manufacturer	Percentage positive test results for *P. falciparum* (Pf line)			Percentage positive test results for *P. falciparum* (Pf line)			Percentage positive test results for *P. falciparum* (pan line)			Percentage positive test results for *P. falciparum* (pan line)			Round
			200 parasites/µL			2000 parasites/µL			200 parasites/µL			2000 parasites/µL			
			Baseline	35 °C	45 °C	Baseline	35 °C	45 °C	Baseline	35 °C	45 °C	Baseline	35 °C	45 °C	
			Number of tests positive			Number of tests positive			Number of tests positive			Number of tests positive			
			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			
Pf, Pv and pan															
Core™ Malaria Pan/Pv/Pf	MAL-190026	Core Diagnostics	100.0	100.0	100.0	100.0	90.0	100.0	0.0	0.0	0.0	80.0	50.0	70.0	3
diagnosticks MALARIA (Pan/Pv/Pf) Cassette	MPNVFC1007.5	SSA Diagnostics & Biotech Systems	96.7	100.0	93.3	100.0	100.0	100.0	0.0	0.0	0.0	70.0	0.0	50.0	3
FirstSign™ - ParaView-3 (Pan+Pv+Pf) Malaria Test	2103 CB-25	Unimed International Inc.	100.0	100.0	100.0	100.0	100.0	100.0	60.0	50.0	15.0	100.0	90.0	100.0	2
Paramax-3 Rapid Test for Malaria Pan/Pv/Pf (device)	50320025	Zephyr Biomedicals	100.0	100.0	100.0	100.0	100.0	100.0	100.0	25.0	30.0	100.0	95.0	100.0	2
Pan only															
Advantage Pan Malaria Card[a]	IR013025	J. Mitra & Co. Pvt. Ltd.	NA	NA	NA	NA	NA	NA	36.7	66.7	60.0	100.0	100.0	90.0	5
AZOG hCG Malaria Detection Test Device	MPT-124	AZOG, INC.	NA	NA	NA	NA	NA	NA	100.0	100.0	100.0	100.0	100.0	100.0	4
CareStart™ Malaria pLDH (PAN)[a]	G0111	Access Bio, Inc.	NA	NA	NA	NA	NA	NA	100.0	100.0	100.0	100.0	100.0	100.0	5
Clearview® Malaria pLDH[a]	70884025	Orgenics Ltd. (Inverness Medical Innovations)	NA	NA	NA	NA	NA	NA	96.7	93.3	100.0	100.0	100.0	100.0	3
diagnosticks MALARIA (Pan) Cassette	MPNWBC1007.3	SSA Diagnostics & Biotech Systems	NA	NA	NA	NA	NA	NA	0.0	0.0	0.0	80.0	100.0	80.0	3
First Response® Malaria Ag pLDH	I12FRC30	Premier Medical Corporation Ltd.	NA	NA	NA	NA	NA	NA	50.0	80.0	55.0	100.0	100.0	100.0	2
FirstSign™ - PanCheck (Pan) Malaria Test	2104 CB-25	Unimed International Inc.	NA	NA	NA	NA	NA	NA	25.0	5.0	10.0	100.0	100.0	100.0	2
OnSight™ - PanScreen (Pan) Malaria Test	539-25-DB	Amgenix International, Inc.	NA	NA	NA	NA	NA	NA	5.0	35.0	15.0	100.0	100.0	100.0	2
Parabank™ Device - Rapid test for Malaria Pan[a]	50301025	Zephyr Biomedical Systems	NA	NA	NA	NA	NA	NA	0.0	0.0	0.0	90.0	100.0	100.0	3
Pv only															
SD BIOLINE Malaria Ag Pv	05FK70	Standard Diagnostics, Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	2

NA, not applicable

Pf, *Plasmodium falciparum* Pv, *Plasmodium vivax* pan, *Plasmodium* species Pvom, *Plasmodium vivax, ovale* and *malariae*

Indicates results for those products that meet all WHO recommended procurement criteria

[a] Product resubmission, results from most recent round of testing replace previous results. Refer to Table S1.

[b] Results presented in the table are based on stability of a Pf test line (either Pf-HRP2 or Pf-pLDH). Results based on stability of individual test lines is presented in the following table:

Product	Catalogue number	Manufacturer	Percentage positive test results for *P. falciparum* (Pf line)			Percentage positive test results for *P. falciparum* (Pf line)			Percentage positive test results for *P. falciparum* (pan line)			Percentage positive test results for *P. falciparum* (pan line)			Round
			200 parasites/µL			2000 parasites/µL			200 parasites/µL			2000 parasites/µL			
			Baseline	35 °C	45 °C	Baseline	35 °C	45 °C	Baseline	35 °C	45 °C	Baseline	35 °C	45 °C	
			Number of tests positive			Number of tests positive			Number of tests positive			Number of tests positive			
			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH) - (PF(HRP2) line)	05FK90	Standard Diagnostics Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	NA
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH)- (PF(pLDH) line)	05FK90	Standard Diagnostics Inc.	0.0	0.0	0.0	33.3	33.3	33.3	NA	NA	NA	NA	NA	NA	NA
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device - (PF(HRP2) line)	MFV-124F	AZOG, INC.	96.7	96.7	100.0	100.0	100.0	100.0	3.3	0.0	0.0	20.0	0.0	0.0	4
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device - (PF(pLDH) line)	MFV-124F	AZOG, INC.	13.3	3.3	6.7	50.0	10.0	50.0	3.3	0.0	0.0	20.0	0.0	0.0	4
SD BIOLINE Malaria Ag Pf/ Pf/ Pv - (PF(HRP2) line)	05FK100	Standard Diagnostics Inc.	100.0	100.0	96.7	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
SD BIOLINE Malaria Ag Pf/ Pf/ Pv - (PF(pLDH) line)	05FK100	Standard Diagnostics Inc.	26.7	3.3	3.3	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4

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ANNEXES

Annex S1: Characteristics of evaluation panels used in rounds 1–5 of WHO malaria RDT product testing, 2008–2013

Currently, the basis for diagnosing malaria with antigen-detecting RDTs is the detection in a patient's blood of one or more target malaria antigens, including HRP2 (*P. falciparum* only), pLDH (*Plasmodium* spp.(pan-pLDH), *P. falciparum* (Pf-pLDH), non-*falciparum* (Pv-pLDH, Pvom-pLDH) and aldolase (all *Plasmodium* spp). The antigen concentration in samples with the same parasite density varies. Therefore, the concentrations of malaria antigens in the samples that comprise evaluation panels must be consistent in successive rounds of WHO malaria RDT product testing to ensure that the results of each round are highly comparable (statistically equivalent).

Therefore, antigen concentrations were quantified in triplicate in all panel samples, including dilution pairs of 200 and 2000 parasites/µL, by quantitative ELISA. Only results that were consistent in the triplicate runs and showed a value factor between the 200 and the 2000 parasites/µL dilutions close to 10 were considered acceptable and eligible for the performance evaluation panel. In some instances, the antigen concentration was below the detection limit of the ELISA, particularly for aldolase, which is present in malaria parasite samples at much lower concentrations than the other two antigens. Samples that gave inconsistent results for more than one of the three antigens were excluded from the panel.

Despite careful standardization of procedures, the tables and figures below show a wide variation in antigen concentrations for the same parasite density. There are a number of possible explanations, including differences in the level of antigen expression by isolates; different durations of infection (accumulating antigens); different parasite growth stages at the time of collection (expressing different levels of antigen); the presence of circulating HRP2 from previous growth cycles; and HRP2 produced by parasites sequestered in the host's vascular tissues that cannot be accounted for in the estimate of parasite density on the blood slide.

Before each round of WHO malaria RDT product testing, the distribution of HRP2, pLDH and aldolase concentrations at 200 parasites/µL dilution of the wild-type *P. falciparum* and wild-type *P. vivax* samples selected for the phase-2 panels were systematically compared with those in the previous round to ensure there was no statistically significant difference. The figures and tables below show the distribution of antigen concentrations in all five performance evaluation panels. No statistically significant differences were seen (Kruskal-Wallis test; $p > 0.15$), confirming that the results of each new round are additive (and comparable) to the previous ones. In the following box and whisker plots, the end of whiskers represent minimum and maximum values; the box represents middle 50% of data and the line through box represents median values; the crosses represent the mean values.

Figure AS1.1: Box-and-whisker plot of distribution of *P. falciparum* HRP2 concentration (ng/mL) in product testing phase 2 (wildtype) panels.

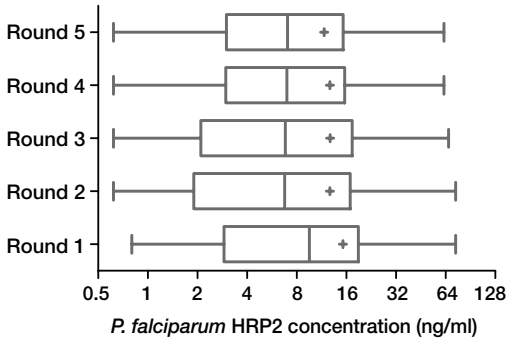


Figure AS1.2: Box-and-whisker plot of distribution of *P. falciparum* pLDH concentration (ng/mL) in product testing phase 2 (wildtype) panels.

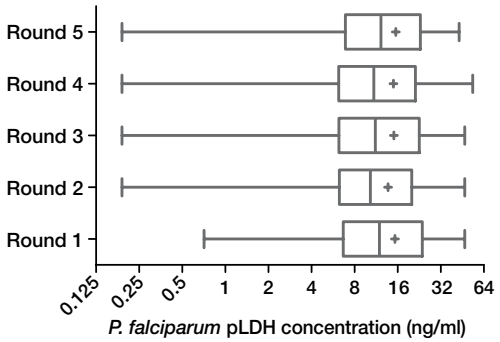


Figure AS1.3: Box-and-whisker plot of distribution of *P. vivax* pLDH concentration (ng/mL) in product testing phase 2 (wild-type) panels.

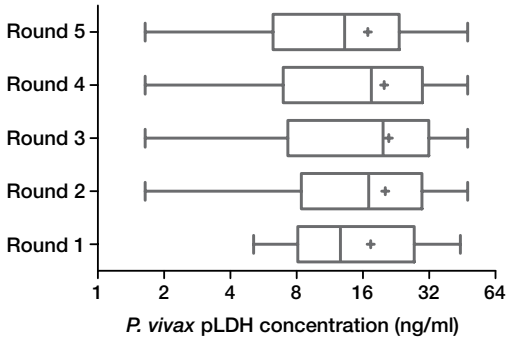


Figure AS1.4: Box-and-whisker plot of distribution of *P. falciparum* aldolase concentration (ng/mL) in product testing phase 2 (wild-type) panels.

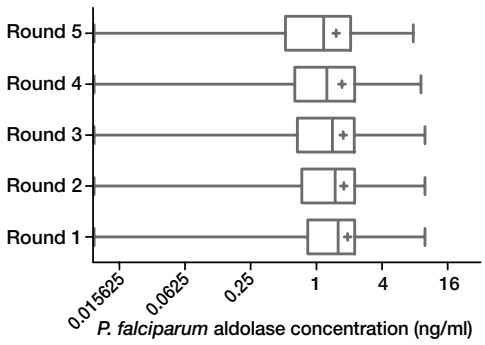


Figure AS1.5: Box-and-whisker plot of distribution of *P. vivax* aldolase concentration (ng/mL) in product testing phase 2 (wild-type) panels.

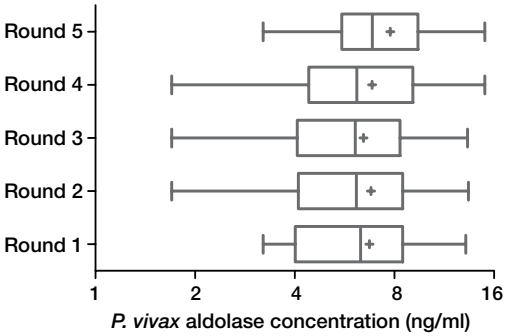


Table AS1.1: Statistics for *P. falciparum* HRP2 concentration (ng/mL) in product testing phase 2 (wild-type) panels.

	Round 1	Round 2	Round 3	Round 4	Round 5
Number of values[a]	78	99	99	98	99
Minimum	0.80	0.62	0.62	0.62	0.62
25% percentile	2.90	1.90	2.10	2.97	3.00
Median	9.57	6.76	6.83	6.98	7.05
75% percentile	18.94	16.91	17.37	15.65	15.31
Maximum	73.70	73.70	66.70	62.48	62.48
Mean	15.28	12.70	12.77	12.72	11.74
Std. Deviation	16.98	15.75	15.19	14.72	13.20

[a] The number of values is the number of samples for which consistent ELISA results were obtained.

Table AS1.2: Statistics for *P. falciparum* pLDH concentration (ng/mL) in product testing phase 2 (wild-type) panels.

	Round 1	Round 2	Round 3	Round 4	Round 5
Number of values[a]	74	93	92	92	94
Minimum	0.71	0.19	0.19	0.19	0.19
25% percentile	6.68	6.27	6.23	6.20	6.90
Median	11.95	10.31	11.18	10.92	12.24
75% percentile	23.75	20.10	22.70	21.28	23.05
Maximum	47.15	47.15	47.15	53.53	43.02
Mean	15.31	13.71	15.08	14.97	15.53
Std. Deviation	11.47	10.90	11.72	11.98	11.43

[a] The number of values is the number of samples for which consistent ELISA results were obtained.

Table AS1.3: Statistics for *P. vivax* pLDH concentration (ng/mL) in wildtype product testing phase 2 (wild-type) panels.

	Round 1	Round 2	Round 3	Round 4	Round 5
Number of values[a]	20	37	33	32	34
Minimum	5.10	1.64	1.64	1.64	1.64
25% percentile	8.10	8.40	7.30	6.96	6.26
Median	12.65	17.00	19.78	17.50	13.22
75% percentile	27.40	29.69	31.89	29.84	23.42
Maximum	44.40	47.90	47.90	47.90	47.90
Mean	17.38	20.24	20.99	20.00	16.84
Std. Deviation	11.57	13.27	13.55	13.00	12.59

[a] The number of values is the number of samples for which consistent ELISA results were obtained.

Table AS1.4: Statistics for *P. falciparum* aldolase concentration (ng/mL) in product testing phase 2 (wild-type) panels.

	Round 1	Round 2	Round 3	Round 4	Round 5
Number of values[a]	77	98	99	98	99
Minimum	0.00	0.00	0.00	0.00	0.00
25% percentile	0.84	0.74	0.67	0.63	0.52
Median	1.61	1.49	1.40	1.25	1.17
75% percentile	2.25	2.25	2.23	2.25	2.07
Maximum	9.90	9.90	9.90	9.08	7.74
Mean	1.93	1.79	1.76	1.72	1.52
Std. Deviation	1.73	1.66	1.69	1.68	1.52

[a] The number of values is the number of samples for which consistent ELISA results were obtained.

Table AS1.5: Statistics for *P. vivax* aldolase concentration (ng/mL) in product testing phase 2 (wild-type) panels.

	Round 1	Round 2	Round 3	Round 4	Round 5
Number of values[a]	20	40	34	33	35
Minimum	3.21	1.70	1.70	1.70	3.21
25% Percentile	4.02	4.11	4.07	4.41	5.55
Median	6.33	6.15	6.10	6.16	6.86
75% Percentile	8.47	8.47	8.32	9.10	9.43
Maximum	13.15	13.40	13.30	15.00	15.00
Mean	6.73	6.81	6.45	6.86	7.78
Std. Deviation	2.89	3.15	2.90	3.23	3.30

[a] The number of values is the number of samples for which consistent ELISA results were obtained.

Annex S2: Malaria RDT field assessment and anomalies

The purpose of this assessment, on a limited number of RDTs, is to assess aspects of packaging, safety and ease-of-use and not to evaluate diagnostic accuracy.

Obtain samples of each malaria RDT under consideration (at least one box packaged as intended for delivery to end users).

Obtain malaria parasite-negative blood samples, and where readily accessible, parasite-positive blood samples for testing against RDTs.

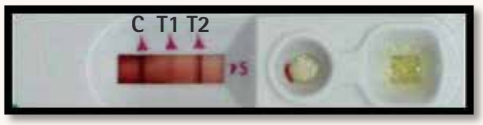
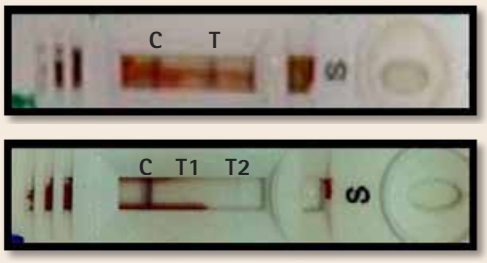
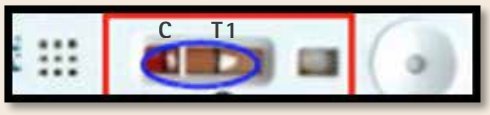
Table AS2.1: Field assessment of RDT packaging, safety and ease-of-use to guide product selection

Date of assessment				
Commercial name				
Catalogue number				
Lot number(s)				
	Yes	**No**	**NA**	**Problems /Comments**
Packaging and accessories				
The RDT box is in good condition				
RDTs are in individual sealed pouches				
The correctly indicated number of RDTs are in the box				
A desiccant is included in each individual RDT pouch				
An expiry date is visible on each RDT pouch				
All required accessories are included in the correct quantities (RDT, buffer, blood transfer device, alcohol swab, lancet, gloves, test tubes (for dipsticks, only)				If no, what is not included:
Instructions				
Instructions are included				
Instructions are in the national language(s)				
The instructions are for the correct product				
The instructions include figures displaying all possible interpretations of the RDT results				
The text and figures are accurate and consistent (specifically order of test lines and results interpretation)				
Preparation and procedure				
The test pouch is easy to open				
It is easy to write on the test device				
The test lines on the device are clearly labelled				
It is easy to use the device for blood collection				
It is easy to open the buffer bottle or ampoule				
The buffer bottle or ampoules have sufficient volume for testing all RDTs in the box				
The buffer bottle or ampoule dispenses even drops				
It is easy to fill the sample well correctly with the provided blood transfer device				
It is easy to fill the buffer well correctly (no overflow)				
The buffer and sample flow well along the test strip				
Result interpretation				
Control and test lines				
Control line is clear				
Test line(s) are clear				
Good clearance of blood by time of reading				If no, number of tests in the box affected:
Steps and reading time				
Reading time <30 min				
Two or fewer timed steps				
Was one or more of the last 10 tests you performed invalid (no control line)?				
If YES, how many?				
Safety				
Are there mixing wells (risk of blood splash)?				
Retractable needle for finger prick?				
Is the RDT in a cassette format (unexposed strip)?				
Have waste disposal safety concerns been addressed? (If no, please describe)				

Figure AS2.1 illustrates examples of RDT observations/anomalies encountered and routinely recorded during Round 5 of WHO Malaria RDT Product Testing at the CDC. In most cases, these anomalies do not invalidate the results, as reactivity in the control and test line areas are still visible, but they may pose challenges to health workers interpreting the results. Furthermore, they should be reported to manufacturers.

An expanded list of notable observations concerning RDT packaging, kit accessories (buffer vials, desiccants) and instructions for use, is under development for use in both product testing and lot testing activities of the WHO-FIND Malaria RDT Evaluation Programme.

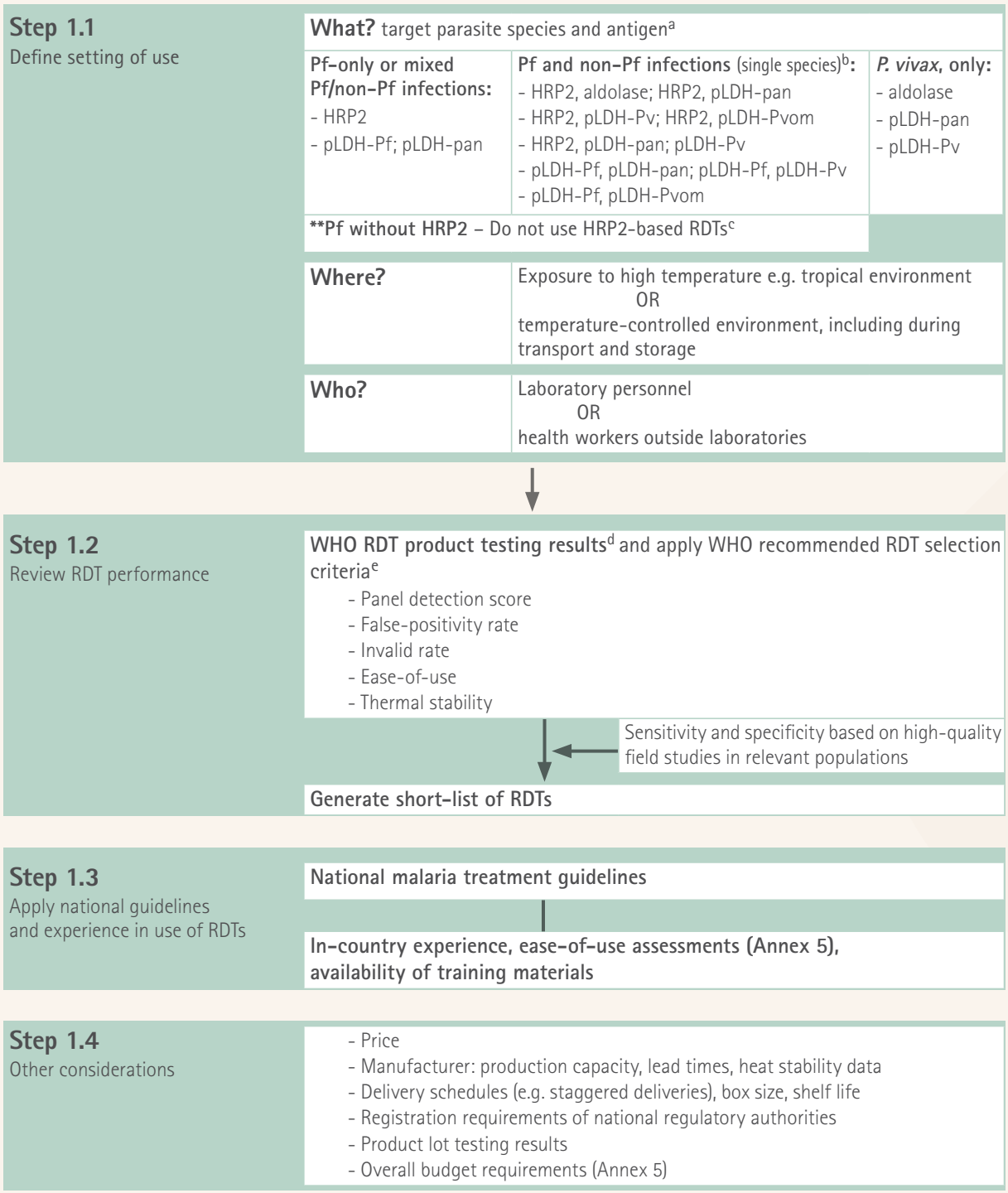
Figure AS2.1: Malaria RDT anomalies encountered in production lots

a) Observations on the test strip		
Red background		Background staining is relatively common. In this example, the result is positive as test lines are positive; however, a more intense red background may obscure weak positive test lines, giving false-negative results
Incomplete clearing		Poor clearing of blood may obscure weak positive test lines, giving false-negative results. In this example, the result is positive as the test line is visible
b) Observations of flow problems		
Failure to flow		Blood and buffer did not run the length of the strip
Irregular migration that obscures test line(s)		One portion of the nitrocellulose near the test band was not absorptive and remained dry during wicking, creating irregular migration of blood/buffer with red background that may obscure test line.
Irregular migration		One portion of the nitrocellulose near the test band was not absorptive and remained dry during wicking, creating irregular migration of blood/buffer with red background. In this example, the result is positive, as the test line is clearly visible.

c) Observations on test lines		
Ghost test lines		*White lines on a stained background. In this example, the result is negative, as the test line is not dark and is thus not visible.*
Patchy broken test line(s)		*The test line is visible but interrupted (broken).*
Diffuse test line(s)		*Test line wider than control, without clearly defined edge.*
d) RDT structural problems		
Strip misplaced in the cassette		*Strip can be seen only partially in the results window.*
Specimen pad not seen in sample window		*Normally, the colour of the conjugated antibody can be seen in the sample window (commonly purple, pink or blue).*

Annex S3: Selection of an appropriate RDT

Figure AS3.1: How to select of an appropriate RDT



[a] Pf-only or mixed Pf/non-Pf infections: Most areas of sub-Saharan Africa and lowland Papua New Guinea; Pf and non-Pf infections (single species): Most endemic areas of Asia and the Americas and isolated areas of the Horn of Africa; Mainly *P. vivax*-only: areas of East Asia, central Asia, South America, and some highland areas elsewhere

[b] Tests with a *P. falciparum*-specific line and pan-specific line will not distinguish *P. falciparum*-only infections from mixed *P. falciparum* infections. Distinguishing *P. falciparum* from mixed *P. falciparum-vivax* infections is important only if a full course of primaquine is routinely given for infections due to *P. vivax*. This must be weighed against the loss of ability to detect *P. malariae* and *P. ovale* if a test has only *P. falciparum*- and *P. vivax*-specific lines. Inclusion of further test lines (e.g. Pf-Pv-pan-pLDH) to detect these increases the complexity of test interpretation. A programme should prioritize these various advantages and disadvantages according to local conditions in the initial stage of making procurement decisions.

[c] *P. falciparum* parasites lacking HRP2 +/- HRP3 genes have been identified with high frequency in parts of South America *(10)*.

[d] See references *(3–6)*.

[e] WHO RDT procurement criteria : http://www.who.int/malaria/publications/atoz/rdt_selection_criteria/en/ (accessed 26 June 2014).

For a comprehensive guide to procurement of malaria RDTs extending beyond selection to quantification, budgeting, technical specifications, management of tenders, contracts, supply management and monitoring of supplier performance and managing product variations, see reference *(13)*.

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